Healthcare improvement based on learning from adverse outcomes

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Move on up toward your destination,
though you may find,
from time to time,
complication

(Curtis Mayfield - Move On Up, 1970)

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Chapter 1

Introduction and outline of the thesis

INTRODUCTION AND OUTLINE OF THE THESIS

The patient safety movement

Healthcare is a high-risk industry in which patients may experience harm that is associated with the care process itself rather than their underlying diseases. This type of harm is commonly referred to as iatrogenic or healthcare-associated harm, with events described as complications or adverse events.[1] Research indicates that nearly 1 out of every 10 patients are affected by adverse events, most of which are related to surgical procedures or medications.[2]

Systematic efforts to prevent adverse events and improve the safety and quality of healthcare can be traced back to pioneers such as nurse Florence Nightingale in the late 1800s, and surgeon Ernest Codman in the early 1900s, who monitored mortality and morbidity rates in their institutions.[3,4] The modern 'patient safety movement', however, is considered to have been launched by the report *To Err is Human* from the US Institute of Medicine, published in November 1999.[5] This report called attention to large national studies in the preceding years, such as the Harvard Malpractice Study,[6,7] which estimated that over half of all fatal adverse events in hospitalized patients resulted from medical errors that could have been prevented. This publication underlined the reality that healthcare was not as safe as it should or could be, and increased public and institutional awareness of the need to improve patient safety.

Similar developments occurred in the Netherlands, where, since 1996, the Quality Law for Healthcare Institutions has required hospitals to systematically monitor, control and improve the quality of their care; a process of self-regulation that was monitored by the Dutch Healthcare Inspectorate.[8] Evaluation of this law in 2001 revealed that little progress had been made towards implementation of formalized systems to improve quality.[9] In response, the Dutch government consulted captains of industry, such as the President of Royal Dutch Shell, for strategies to facilitate improvement in healthcare. In a report in 2004, Shell recommended that hospitals should implement more robust safety management systems.[10] Subsequently, a dedicated task force formulated the basic requirements for such systems in a national stakeholders agreement in 2007.[11] These requirements included practices such as a hospital-wide incident reporting system and form the basis for external hospital audits. In 2015, the Dutch government enacted a new law on healthcare quality ('WKKGZ'), requiring all hospitals to have an incident reporting system as well as an officer for patient complaints.[12]

The increased focus on quality and safety in healthcare resulted in the implementation of various systems to gather information on patient outcomes. The report *To Err is Human* encouraged hospitals to develop and participate in adverse event reporting systems.[5] In fact, roughly 20% of the report dealt with some aspect of reporting.[13] Equally so, national governments have encouraged and enforced reporting of adverse events and serious incidents in healthcare institutions. In the late 1990s, the Dutch surgical society developed a national, standardized system for routine doctor-driven reporting of adverse events.[14,15] The presence of an adverse event reporting system has been included in the list of 'quality indicators' for

hospitals of the Dutch Healthcare Inspectorate since 2004.[16] In that year, at least 75% of the Dutch hospitals had adverse event registries for interventional specialties, such as surgery, gynecology and orthopedics.[16] It remained unclear, however, whether all this information was actually useful in helping to improve the quality and safety of healthcare.

Learning from adverse events: morbidity and mortality conferences

By 2007, more than 80% of all Dutch hospitals reported routinely discussing data from adverse event registries with their teams.[17] The traditional format for periodic discussions of cases with adverse events is commonly known as the 'morbidity and mortality conference' (M&M). At M&M, physicians review past cases to find opportunities to improve care for future patients. This practice emerged in the early 20th century, when the first medical specialties, particularly anesthesiology and surgery, started to openly discuss cases with substandard outcomes as these were expected to reflect substandard care.[4] Currently, M&M is standard practice for most medical specialties around the world and mandated by many residency programs as part of specialty training.[18,19] While it is one of the oldest practices for learning from adverse events in healthcare, there is no definitive evidence that M&M conferences are effective in improving the quality and safety of care.[20,21] Despite the widespread use of these conferences, the format used for M&M varies greatly between departments and hospitals,[21–23] and a gold standard or best practice for M&M is lacking.

It is clear that more research is warranted to understand the key elements required to maximize the value of M&M, and to inform the development of best practices.[24] One benefit of the current practice variation in M&M practice is that it allows a comparison of the relative strengths and weaknesses of different formats. However, while this practice has been frequently studied, few studies provide a comprehensive description of the conference's goals, structure (e.g. audience, timing), and process or content (e.g. case selection, presentation).[22] Additionally, M&M is usually viewed as an educational conference where the objective of improving quality is realized through education about how something *should have* been done differently. However, with the rise of the 'patient safety movement', there was a growing belief that this conference should be used not only to teach but also to collectively seek ways to improve the system in general. Thus, identifying system-level improvements became an additional objective of M&M. It remains unclear, however, to what extent the M&M conference has actually evolved to meet this contemporary expectation. Moreover, there is a paucity of qualitative research on the actual learning process that occurs at M&M and the mechanisms by which this learning leads to positive changes in clinical practice. This is a missed opportunity as qualitative methods may provide rich and nuanced information[25] that quantitative methods cannot reveal. For example, while learning and change theories stipulate that learning is affected by individual and team factors, little is known about the role of these factors in M&M practice.

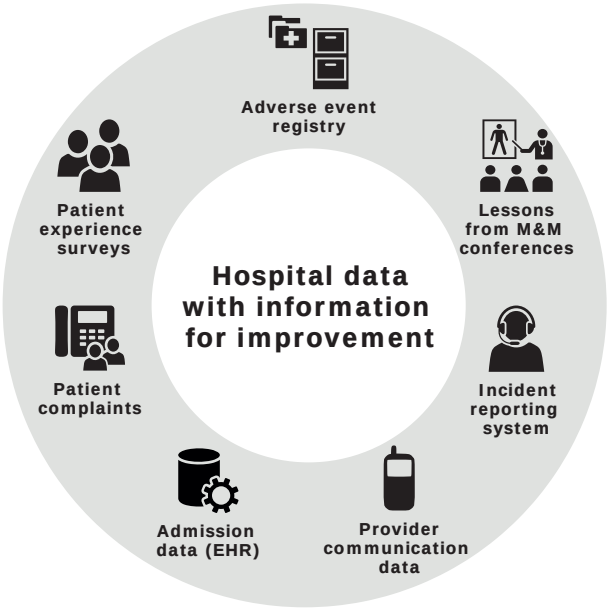
Even though the literature commonly highlights the need for an atmosphere that is free of 'shame and blame' to support open discussions at M&M, the key components of such an atmosphere, and how to support them, remain poorly understood. One theory that offers suggestions on how to harness a culture of learning and trust is 'Just Culture', which has received increased attention in healthcare in recent years.[26–29] Just Culture is based on the principle that professionals should not be punished for unintended adverse outcomes.[30] This theory stipulates that when learning is the objective, such as in M&M or further study of cases with adverse outcomes, blame or culpability should be avoided because these pose a serious threat to the learning process. While most hospitals aim to achieve a blame-free culture that promotes learning, research indicates that crucial aspects of Just Culture may not be fully understood, may be difficult to implement or are perhaps lost in translation from theory to healthcare practice.[31]

In general, research into M&M practice is hampered by a variety of factors, including the fundamental problem that there is currently no adequate agreed measure of success. The conference aims to improve healthcare quality and safety through learning from past cases, therefore the apparent measure of success should be improvements in these domains, such as a decrease in adverse event rates. However, it would be unrealistic to use these rates as a measure of M&M output, because the impact of M&M on these outcomes cannot be isolated from other, simultaneous, advancements in clinical practice. Instead, the lessons and plans for improvement that are derived from M&M may serve as an initial measure of its success.[24] Most M&Ms, however, do not routinely document these plans or lessons learned, which makes it difficult to use these data for research or monitoring purposes.[32] While some studies have been able to investigate the improvement plans that derived from M&Ms, they had only limited amounts of data and provided few details on what was actually learned or targeted for improvement.[33–35]

Learning from other hospital data

Hospitals routinely collect various types of information on the quality and safety of their care, and specifically, data on various types of adverse outcomes, such as adverse events and incidents (Figure 1). Adverse events concern patient harm, regardless of whether this has been the result of suboptimal care. Incidents refer to suboptimal processes, regardless of whether these have inflicted patient harm. Incidents can be reportable circumstances, near misses (e.g., medication error that was prevented), no harm incidents (e.g., medication error that did not cause harm) or harmful incidents (i.e., causing adverse events).[36] A harmful incident that causes a severe adverse event is considered a 'sentinel event'. Dutch hospitals are required to report sentinel events, as well as a subsequent investigation report, to the Healthcare Inspectorate. Adverse events and incidents are for local review only, with adverse events usually reported by clinicians[15] or identified through retrospective record review,[37] and incidents mostly reported by nurses.[38,39]

Figure 1. Hospital data that can serve as a source of information for improvement used in the research presented in this thesis.



Other information sources are available that reflect the patient perspective on quality and safety. Patients have long been able to file a complaint or claim against hospitals, but this remained a primarily a concern of legal departments rather than hospital quality departments. The problems raised in complaint letters are often complementary to those identified by other systems of monitoring, such as incident reporting or record review.[39,40] Patient experience has become increasingly recognized as a central pillar of quality in healthcare, which led to a more systematic collection of patient-reported experience and satisfaction data.[41–43] National patient experience surveys emerged around the world, particularly between 2002 and 2006.[44–46] It is intuitive that patient experience would be affected by adverse outcomes, and although there is evidence in this direction,[47] relationships between patient experience and patient safety remain poorly understood.[48] Patients may not always be in the position to identify specific adverse events,[49] but they may be able to report on underlying problems that have contributed, such as the quality of doctor-patient communication.[50] Greater insight into the relation between patient experience and adverse outcomes could be used to identify signals that forewarn a negative patient experience so that providers could intervene earlier and, on a more general level, improve our responses to patients' needs to ensure a positive experience.

The described systems to collect quality and safety data (Figure 1) have been instituted at different times and for different purposes. As a result, their data are mostly stored and used in isolation from each other. Connecting patient experience data in closer connection to other data sources is further hindered by the fact that these data are usually anonymized,[51]

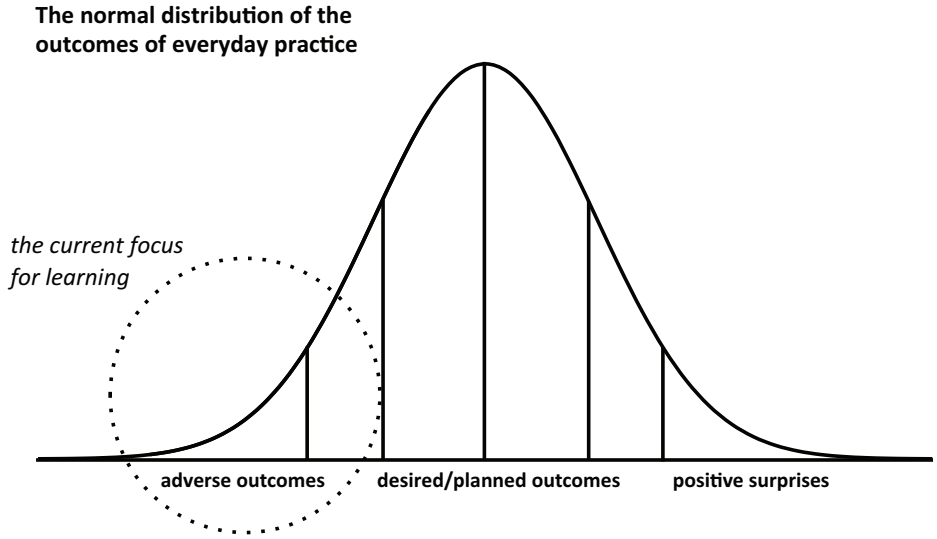
preventing linkage with admission or safety data. Prior studies have demonstrated that each of these data systems reveal different types of safety issues,[39,52,40,53] and recommend that hospitals use more than one method. However, while these systems collect different signals from the same 'patient journey', they are likely to be related at the patient level as events may trigger each other and potentially lead to a cascade of events (e.g., incident → adverse event → negative patient experience → complaint). These relations remain obscured by the currently isolated data sources, but in a research setting, these data could be linked to each other to study potential clustering of these events, and to explore whether data linkage could reveal additional information for improvement that use of individual sources may not provide.

Another potential source of valuable information is the hospital communication data, which could be used to investigate clinicians' workload, work flow interruptions, and inefficiencies in hospital communication,[54] all of which are relevant for safety and quality of care. A method that is widely used for communication within hospitals, particularly in the United States, is text paging.[55–57] Text paging generates large volumes of free-text data, as a single physician may receive approximately 60 messages per shift.[54] While not commonly used for this purpose, assessment of the frequency and timing as well as the content of these pages may reveal recurring issues and bottlenecks in care processes.

Learning from everyday practice

The traditional approach to safety alerts us to the *absence* of safety by signaling and assessing situations where things go wrong, but this tells us little about the *presence* of safety when things go right (Figure 2).[58,59] A focus on situations where there was an absence of safety is a logical and seemingly efficient approach, because these situations are thought to most likely contain opportunities for improvement. However, this strategy has various limitations, which may render some of the conclusions invalid. Identifying 'errors' is biased by retrospection (hindsight bias), knowledge of the outcome (outcome bias) and by the fact that reviewers always have a different perspective than those making decisions in the face of complexity and uncertainty (outsider bias). Moreover, such a 'find and fix' approach assumes that a specific bad component can be identified and changed for the better. In reality, however, healthcare is a complex adaptive system in which many human and technological actors interact in various ways.[60] Therefore, individual components cannot be assessed in isolation but rather must be seen as part of an interdependent whole. Likewise, a component cannot be changed in isolation without affecting other parts of the system. Changes that are based on a single undesired exceptional case could even, inadvertently, hamper the system's ability to succeed (e.g., additional checks may increase complexity and inefficiency). A sole focus on cases with adverse outcomes (Figure 2) thus fails to consider that most of the time, the same staff and care processes and perhaps very similar situations, have led to desired outcomes. Ironically, because desired outcomes are seen as 'normal', these are often referred to as situations where 'nothing happens'.[60]

Figure 2. The normal distribution of outcomes of everyday work and the current focus for learning.



Adapted from Hollnagel E (2015).[76]

The notion that we should not change the whole system in reaction to a non-representative event bears some similarity to the concept of 'common vs. special cause variation' in statistical process control theory, a scientific method developed in the 1920s.[61] The method cautions to not react to special cause variation as if it were common. If a severe adverse outcome may be considered a form of special cause variation, this would also imply that it should not serve as the basis for systemic changes. This theory furthermore stipulates that processes with this type of variation are unstable and unpredictable,[62] which is a characterization that can be made for healthcare settings in general.[59] Moreover, it is questionable whether we have an accurate and complete view of how the particular work is actually carried out. The renowned W. Edwards Deming remarked: *"If you can't describe what you're doing as a process, you don't know what you are doing*".[63] Nevertheless, many descriptions may still be inaccurate, because how a process works in theory can be quite different from how it is actually carried out in the imperfect and messy reality of everyday practice in healthcare.

Understanding everyday practice, and how it usually leads to desired outcomes, is a key element of proactive approaches to safety that emerged in the wider field of safety science,[60,64] and found their way to healthcare between 2012 and 2015.[59,65–67] These new approached aim to proactively learn from *everyday* practice, and seek to understand how things mostly "go right" as an explanation for how things sometimes "go wrong".[59,60,68] After all, regardless of the outcomes, all performance ultimately flows from the same underlying processes, with the same behaviors and practices.[59] Therefore, if we want to support and enhance the capacity for safe performance, we must first increase our understanding of everyday practice (work-

as-done), and how this relates to concepts of how work is done held by those removed from the sharp end (work-as-imagined).[60] Currently there is only limited research on how this approach could best be used to enhance healthcare improvement and questions remain about how exactly we can learn from everyday practice rather than specifically defined cases as well as what should we study, how and when. One method that has been developed to study everyday practice is the Functional Resonance Analysis Method (FRAM), which visualizes essential activities of a work process, including their interactions and variability.[69] Renowned safety experts, such as James Reason, have endorsed this method and the underlying theory as a way forward to improve safety in complex systems, such as healthcare.[70] While FRAM has been used in other industries, such as aviation and air traffic management,[71–73] uptake is still limited in the medical field.[74,75]

Aims and outline of this thesis

The objective of this PhD thesis was to study how processes for learning from adverse outcomes could be optimally used, both individually and collectively, to continuously improve healthcare. Specific research questions included:

How can we learn most effectively from adverse outcomes:

(i) based on case discussions at morbidity and mortality conferences;

(ii) by integrating available aggregate-level data (eg, incidents, patient experiences);

(iii) in context of everyday practice that produces adverse as well as desired outcomes; in order to continuously improve healthcare?

The first three chapters of this thesis present quantitative and qualitative studies with the aim of identifying factors for successful learning from adverse events discussed at morbidity and mortality conferences, healthcare's oldest practice for learning and improvement.

In **chapter 2,** the study objective was to identify strengths and challenges of different formats for M&M, comparing surgical M&M practices of an American and Dutch teaching hospital, as well as their participants' expectations and experiences.

Chapter 3 assesses factors that may hamper or facilitate success of M&M (i.e., whether learning and improvement occurs), through qualitative analysis of semi-structured interviews with the conference's participants.

In **chapter 4**, the frequency and type of lessons for patient care identified during eight years of surgical M&M were studied to assess the focus and sustainability of learning at this conference.

The following chapters examine how integration with other types of routinely collected data could further enhance learning and improvement processes in hospitals.

In **chapter 5,** independent data collection systems for patient complaints, incidents and adverse events, were linked at the patient level to assess the complex relationship between

events co-occurring in admissions, which may reveal valuable information for improvement efforts.

The value of information from the patient perspective is more closely examined in **chapter 6** and **chapter 7,** which examine the use of patient complaint letters and the use of patient experience survey data for improvement respectively.

Chapter 8 aims to study how hospital communication data, obtained from text paging between clinicians, may help to identify domains for improvement of patient care. The technique of natural language processing is used to examine this information source with large volumes of free-text data.

The potential value of learning from everyday practice was examined in the next two chapters. Well-known problem areas may best serve as targets for these types of studies that seek to understand how a process usually ensures safe and high-quality care. Therefore, in **Chapter 9,** the process of preoperative anticoagulation management was studied in an Australian and Dutch teaching hospital using FRAM. The aim of this study was to examine the usability and value of FRAM for safety improvement in healthcare. **Chapter 10** presents a perspective on how principles of the Safety-II and Just Culture theories on learning from everyday practice in a culture of trust, learning and accountability, could be applied to learning from sentinel events in healthcare.

Chapter 11 provides a general discussion with future perspectives, and a summary is enclosed in **chapter 12**.

GLOSSARY OF TERMS

Adverse outcomes	Term used in this thesis to refer to adverse events, incidents, sentinel events, patient complaints and negative patient experiences.
Adverse event[1]	An undesired patient outcome that may or may not be the result of an error; sometimes referred to as a 'complication'.
Incident[2]	An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.
Medical error[3]	An adverse event or near miss that is preventable with the current state of medical knowledge.
M&M[4]	The morbidity and mortality conference, a traditional forum that provides clinicians with an opportunity to discuss medical error and adverse events.
Patient safety[5]	The avoidance, prevention and amelioration of adverse outcomes or injuries associated stemming from the processes of healthcare.
Second victims[6]	Healthcare professionals who have been involved in a patient safety incident, medical error or adverse event, for which they feel personally responsible and experience emotional distress.
Sentinel event	Harmful incident that causes a severe adverse event. In the Netherlands, these cases need to be reported to the Dutch Healthcare Inspectorate.

[1]Thomas EJ, Brennan TA. Errors and adverse events in medicine: An overview. In: Vincent C, ed. Clinical Risk Management: Enhancing Patient Safety. London: BMJ Publishing, 2001, pp. 31–43.

[2] World Health Organization. The Conceptual Framework for the International Classification for Patient Safety. Version 1.1. Final Technical Report. 2009. Available from http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf (Accessed 8 September 2017)

[3] Quality Interagency Coordination Task Force. Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact. Washington, DC: Quality Interagency Coordination Task Force, 2000.

[4] Deis et al. Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement. Agency for Healthcare Research and Quality (US); 2008. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21249895 (Accessed 8 September 2017)

[5] Vincent C. Patient Safety. Edinburgh: Elsevier Churchill Livingston, 2006

[6] Dekker SWA. Second victim: Error, guilt, trauma and resilience. Boca Raton, FL, CRC Press/Taylor & Francis, 2013.

REFERENCES

1. World Health Organization. *The Conceptual Framework for the International Classification for Patient Safety. Version 1.1. Final Technical Report.*; 2009. http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf
2. de Vries EN, Ramrattan MA, Smorenburg SM, et al. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care*. 2008;17:216-223. doi:10.1136/qshc.2007.023622.
3. McDonald L. Florence Nightingale and the early origins of evidence based nursing. *Evid Based Nurs*. 2001;4:68-69.
4. Orlander JD, Barber TW, Fincke BG. The morbidity and mortality conference: the delicate nature of learning from error. *Acad Med*. 2002;77:1001-1006. doi:10.1097/00001888-200210000-00011.
5. Kohn LT, Corrigan JM, Donaldson M. *To Err Is Human: Building a Safer Health System*. Washington DC, USA: National Academy Press; 1999.
6. Brennan T, Leape LL, Laird N, et al. INCIDENCE OF ADVERSE EVENTS AND NEGLIGENCE IN HOSPITALIZED PATIENTS: Results of the Harvard Medical Practice Study I. *N Engl J Med*. 1991;324:370-376.
7. Leape LL, Brennan TA, Laird NAN, et al. Harvard Medical Practice Study II. 1991;324(6):377-384.
8. Quality Act Healthcare Institutions 1996 (Dutch). Available from *http://wetten.overheid.nl/BWBR0007850/2015-01-01* (Accessed 11 September 2017).
9. Borst-Eilers E. Letter of the Minister of Health, Welfare and Sport to the House of Representatives. 10 June 2002.
10. Willems R. Hier Werk Je Veilig, of Je Werkt Hier Niet (Dutch); 2004 Available from *http://www.vmszorg.nl/_library/14216/rapport_rein_willems_2004.pdf* (Accessed 12 September 2017).
11. VMSzorg. The Dutch patient safety programme. Available from *https://www.vmszorg.nl/praktijkvoorbeelden-en-tools/international-toolkit/* (Accessed 8 March 2018).
12. Healthcare Quality, Complaints and Disputes Act (WKKGZ). Available from: *https://www.government.nl/topics/quality-of-healthcare/healthcare-quality-complaints-and-disputes-act-wkkgz* (Accessed 12 September 2017).
13. Wears RL, Kneebone R, Wears R, et al. Learning from near misses in aviation: so much more to it than you thought. *BMJ Qual Saf*. 2016;26:513-514. doi:10.1136/bmjqs-2016-005990.
14. Marang-van de Mheen PJ, Stadlander MC, Kievit J. Adverse outcomes in surgical patients: implementation of a nationwide reporting system. *Qual Saf Health Care*. 2006;15:320-324. doi:10.1136/qshc.2005.016220.
15. Kievit J, Krukerink M, Marang-van de Mheen PJ. Surgical adverse outcome reporting as part of routine clinical care. *Qual Saf Health Care*. 2010;19:e20. doi:10.1136/qshc.2008.027458.
16. Dutch Healthcare Inspectorate. The Result Counts 2004 (Dutch). The Hague, the Netherlands; 2006. Available from *www.igz.nl/zoeken/download.aspx?download=Het+resultaat+telt+2004.pdf* (Accessed 12 September 2017).
17. Dutch Healthcare Inspectorate. *The Result Counts 2007 (Dutch)*. The Hague, the Netherlands; 2008. Available from *www.igz.nl/zoeken/download.aspx?download=Het+resultaat+telt+2007.pdf* (Accessed 12 September 2017).
18. *Kaderbesluit CCMS (Dutch)*; 2014. Available from *http://knmg.artsennet.nl/Opleiding-en-herregistratie/CGS/Regelgeving/Huidigeregelgeving.htm* (Accessed 12 September 2017).
19. *ACGME Program Requirements for Graduate Medical Education in General Surgery*. Chicago, IL. Available from: https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/440_general_surgery_2017-07-01.pdf. (Accessed 12 September 2017).

20. Berenholtz SM, Hartsell TL, Pronovost PJ. Learning from defects to enhance morbidity and mortality conferences. *Am J Med Qual*. 2009;24:192-195. doi:10.1177/1062860609332370.
21. Aboumatar H, Blackledge C, Dickson C, et al. A Descriptive Study of Morbidity and Mortality Conferences and Their Conformity to Medical Incident Analysis Models: Results of the Morbidity and Mortality Conference Improvement Study, Phase 1. *Am J Med Qual*. 2007;22:232-238.
22. Xiong X, Johnson T, Jayaraman D, et al. At the Crossroad with Morbidity and Mortality Conferences: Lessons Learned through a Narrative Systematic Review. *Can J Gastroenterol Hepatol*. 2016;2016:7679196. doi:10.1155/2016/7679196.
23. Sellier E, David-Tchouda S, Bal G, et al. Morbidity and mortality conferences: their place in quality assessments. *Int J Health Care Qual Assur*. 2012;25:189-196. doi:10.1108/09526861211210411.
24. Tad-y D, Wald HL. The evolution of morbidity and mortality conferences. *BMJ Qual Saf*. 2017;26:433-435. doi:10.1136/bmjqs-2016-005817.
25. DiCicco-Bloom B, Crabtree BF. The qualitative research interview. *Med Educ*. 2006;40:314-321. doi:10.1111/j.1365-2929.2006.02418.x.
26. Dekker SWA, Hugh TB. A just culture after Mid Staffordshire. *BMJ Qual Saf*. 2014;23:356-358. doi:10.1136/bmjqs-2013-002483.
27. Dekker SWA. Prosecuting professional mistake: Secondary victimization and a research agenda for criminology. *Int J Crim Justice Sci – Off J South Asian Soc Criminol Vict*. 2009;4:973-5089.
28. Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: The tools to achieve high reliability. *Health Serv Res*. 2006;41:1690-1709. doi:10.1111/j.1475-6773.2006.00572.x.
29. Martinez W, Lehmann LS, Hu Y-Y, et al. Processes for Identifying and Reviewing Adverse Events and Near Misses at an Academic Medical Center. *Jt Comm J Qual Patient Saf*. 2017;43:5-15. doi:10.1016/j.jcjq.2016.11.001.
30. Dekker SWA. *Just Culture: Restoring Trust and Accountability in Your Organization*. Taylor & Francis Ltd; 2016.
31. Heijboer L, Heuver G, Schilp J, Wagner C. "Just Culture": inzicht in calamiteitenbeleid in Nederlandse zorginstellingen (Dutch). *KiZ*. 2015;25:24-27.
32. Antonacci AC, Lam S, Lavarias V, et al. A Morbidity and Mortality Conference-Based Classification System for Adverse Events: Surgical Outcome Analysis: Part I. *J Surg Res*. 2008;147:172-177. doi:10.1016/j.jss.2008.02.054.
33. François P, Prate F, Vidal-Trecan G, et al. Characteristics of morbidity and mortality conferences associated with the implementation of patient safety improvement initiatives, an observational study. *BMC Health Serv Res*. 2016;16:35. doi:10.1186/s12913-016-1279-8.
34. Bechtold ML, Scott S, Dellsperger KC, et al. Educational quality improvement report: outcomes from a revised morbidity and mortality format that emphasised patient safety. *Postgrad Med J*. 2008;84:211-216. doi:10.1136/qshc.2006.021139.
35. Kauffmann RM, Landman MP, Shelton J, et al. The Use of a Multidisciplinary Morbidity and Mortality Conference to Incorporate ACGME General Competencies. *J Surg Educ*. 2011;68:303-308. doi:10.1016/j.jsurg.2011.02.002.
36. World Alliance for Patient Safety. *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems*. Geneva: World Health Organization; 2005.
37. Baines RJ, Langelaan M, de Bruijne MC, et al. Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ Qual Saf*. 2013;22:290-298. doi:10.1136/bmjqs-2012-001126.

38. Rowin EJ, Lucier D, Pauker SG, et al. Does Error and Adverse Event Reporting by Physicians and Nurses Differ? *Jt Comm J Qual Patient Saf*. 2008;34:537-545.
39. Christiaans-Dingelhoff I, Smits M, Zwaan L, et al. To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports? *BMC Health Serv Res*. 2011;11:49. doi:10.1186/1472-6963-11-49.
40. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, DC: National Academy Press; 2001.
41. Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open*. 2013;3:e005170. doi:10.1136/bmjopen-2012-001570.
42. World Health Organization. *Patients for Patient Safety*. Geneva: World Health Organization; 2007.
43. DeCourcy A, West E, Barron D. The National Adult Inpatient Survey conducted in the English National Health Service from 2002 to 2009: how have the data been used and what do we know as a result? *BMC Health Serv Res*. 2012;12:71. doi:10.1186/1472-6963-12-71.
44. HCAHPS Fact Sheet. June 2015. Centers for Medicare & Medicaid Services (CMS). Baltimore, MD, USA. http://www.hcahpsonline.org/Files/HCAHPS_Fact_Sheet_June_2015.pdf (Accessed 20 October 2017).
45. Triemstra M, Winters S, Kool RB, et al. Measuring client experiences in long-term care in the Netherlands: a pilot study with the Consumer Quality Index Long-term Care. *BMC Health Serv Res*. 2010;10:95. doi:10.1186/1472-6963-10-95.
46. Marang-van de Mheen PJ, van Duijn-Bakker N, Kievit J. Surgical adverse outcomes and patients' evaluation of quality of care: inherent risk or reduced quality of care? *Qual Saf Heal Care*. 2007;16:428-433. doi:10.1136/qshc.2006.021071.
47. Weissman JS, López L, Schneider EC, et al. The association of hospital quality ratings with adverse events. *Int J Qual Heal Care*. 2014;26:129-135. doi:10.1093/intqhc/mzt092.
48. Fowler F, Epstein A, Weingart S, et al. Adverse Events During Hospitalization: Results of a Patient Survey. *Jt Comm J Qual Patient Saf*. 2008;34:583-590. doi:10.1016/S1553-7250(08)34073-2.
49. Carter J, Ward C, Wexler D, et al. The association between patient experience factors and likelihood of 30-day readmission: a prospective cohort study. *BMJ Qual Saf*. 2017 Nov 16 [Epub ahead of print]. doi:10.1136/bmjqs-2017-007184.
50. Flott KM, Graham C, Darzi A, et al. Can we use patient-reported feedback to drive change? The challenges of using patient-reported feedback and how they might be addressed. *BMJ Qual Saf*. 2017;26:502-507. doi:10.1136/bmjqs-2016-005223.
51. Olsen S, Neale G, Schwab K, et al. Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place. *Qual Saf Heal Care*. 2007;16:40-44. doi:10.1136/qshc.2005.017616.
52. Levtzion-Korach O, Frankel A, Alcalai H, et al. Integrating Incident Data from Five Reporting Systems to Assess Patient Safety: Making Sense of the Elephant. *Jt Comm J Qual Patient Saf*. 2010;36:402-410. doi:10.1016/S1553-7250(10)36059-4.
53. Sari A, Sheldon T, Cracknell A, et al. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *Br Med J*. 2007;334(7584):79. doi:10.1136/bmj.39031.507153.AE.
54. Patel SP, Lee JS, Ranney DN, et al. Resident workload, pager communications, and quality of care. *World J Surg*. 2010;34:2524-2529. doi:10.1007/s00268-010-0740-9.
55. Nguyen T, Battat A, Longhurst C, et al. Alphanumeric paging in an academic hospital setting. *Am J Surg*. 2006;191:561-565.

56. Carlile N, Rhatigan J, Bates D. Why do we still page each other? Examining the frequency, types and senders of pages in academic medical services. *BMJ Qual Saf*. 2017;26:24-29. doi: 10.1136/bmjqs-2015-004587
57. Etchells E, Adhikari N, Wu R, et al. Real-time automated paging and decision support for critical laboratory abnormalities. *BMJ Qual Saf*. 2011;20:924-930. doi: 10.1136/bmjqs.2010.051110
58. Lawton R, Taylor N, Clay-Williams R, et al. Positive deviance: a different approach to achieving patient safety. *BMJ Qual Saf*. 2014;23:880-883. doi:10.1136/bmjqs-2014-003115.
59. Braithwaite J, Wears RL, Hollnagel E. Resilient health care: Turning patient safety on its head. *Int J Qual Heal Care*. 2015;27:418-420. doi:10.1093/intqhc/mzv063.
60. Hollnagel E. *Safety-I and Safety-II. The Past and Future of Safety Management*. Ashgate Publishing Limited, ed. Farnham, UK; 2014.
61. Shewart W. *The Economic Control of Quality of a Manufactured Product*. D van Nostrand, ed. New York; 1931.
62. Benneyan JC, Lloyd RC, Plsek PE. Statistical process control as a tool for research and healthcare improvement. *Qual Saf Heal Care*. 2003;12:458-464. doi:10.1136/qhc.12.6.458.
63. Deming W. *Out of the Crisis*. Cambridge, MA: Massachusetts Institute of Technology Center for Advanced Engineering Study xiii; 1986.
64. Besnard D, Hollnagel E. I want to believe: some myths about the management of industrial safety. *Cogn Technol Work*. 2014;16:13. doi:10.1007/s10111-012-0237-4
65. Hollnagel E, Leonhardt J, Licu T, et al. From Safety-I to Safety-II: a white paper. Brussels: EUROCONTROL. 2013. Available from https://www.skybrary.aero/bookshelf/books/2437.pdf (Accessed 1 September 2017).
66. Hamming JF, Gans ROB. Leren van dingen die goed gaan (Dutch). *Med Contact (Bussum)*. 2014;46.
67. Feeley D. Six Resolutions to Reboot Patient Safety. Institute for Healthcare Improvement; 2017.http://www.ihi.org/communities/blogs/_layouts/15/ihi/community/blog/ItemView.aspx?List=7d1126ec-8f63-4a3b-9926-c44ea3036813&ID=365&Web=1e880535-d855-4727-a8c1-27ee672f115d (Accessed 1 September 2017).
68. Hollnagel E, Wears R, Braithwaite J. *From Safety-I to Safety-II: A White Paper*. Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia; 2015. https://resilienthealthcare.net/wp-content/uploads/2018/05/WhitePaperFinal.pdf (Accessed 9 February 2017).
69. Hollnagel E, Hounsgaard J, Colligan L. *FRAM – The Functional Resonance Analysis Method – A Handbook for Practical Use of the Method*. Middelfart, Denmark; 2014. http://functionalresonance.com/onewebmedia/FRAM_handbook_web-2.pdf (Accessed 9 February 2017).
70. Reason J. *Organizational Accidents Revisited*. Farnham, Surrey, UK: Ashgate Publishing; 2016.
71. Nouvel D, Travadel S, Hollnagel E. Introduction of the Concept of Functional Resonance in the Analysis of a Near-Accident in Aviation. Introduction of the Concept of Functional Resonance in the Analysis of a Near-Accident in Aviation.. 33rd ESReDA Seminar: Future challenges of accident inv. In: *33rd ESReDA Seminar: Future Challenges of Accident Invesitgation*. Ispra, Italy; 2007:9p. https://hal-mines-paristech.archives-ouvertes.fr/hal-00614258.
72. Woltjer R. Functional Modeling of Constraint Management in Aviation Safety and Command and Control [Doctoral thesis]. 2009. http://liu.diva-portal.org/smash/get/diva2:210824/FULLTEXT01.pdf (Accessed 22 August 2017).
73. De Carvalho PVR. The use of Functional Resonance Analysis Method (FRAM) in a mid-air collision to understand some characteristics of the air traffic management system resilience. *Reliab Eng Syst Saf*. 2011;96:1482-1498. doi:10.1016/j.ress.2011.05.009.

74. Hounsgaard J. Patient safety in everyday work. Learning from what goes right [MSc thesis]. University of Southern Denmark; 2016. http://functionalresonance.com/onewebmedia/Hounsgaard%20(2016).pdf (Accessed 9 February 2017).
75. Clay-Williams R, Hounsgaard J, Hollnagel E. Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implement Sci*. 2015;10:125. doi:10.1186/s13012-015-0317-y.
76. Hollnagel E. Is there a "Safety-III"? 2015 http://safetysynthesis.com/safetysynthesis-facets/safety-i-and-safety-ii/and%20what%20about%20safety-iii.html (Accessed 17 April 2018).

Chapter 2

Toward best practices for surgical morbidity and mortality conferences: a mixed method study

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ABSTRACT

Objective

To assess formats for surgical morbidity and mortality conferences (M&M) for strengths and challenges.

Design

A mixed methods approach with local observations to assess key domains of M&M practice (i.e., goals, structure, and process/content) and surveys to assess participants' expectations and experiences.

Setting

Surgical departments of two teaching hospitals (Boston, USA, and Leiden, Netherlands).

Participants

Participants of surgical M&M, including attending surgeons, residents, physician assistants, and medical students (total n = 135).

Results

Surgical M&M practices at both hospitals had education as its overarching goal, but varied in structure and process/content. Expectations were similar at both sites with ≥ 80% of participants (n = 90; 67% response) expecting M&M to be focused on education as well as quality improvement (QI), blame-free, mandatory for both residents and attendings, and to lead to changes in clinical practice. However, compared to expectations, significantly fewer participants at both sites experienced: a QI focus (both P<.001); mandatory faculty attendance (P=.004; P<.001) and changes to practice (both P<.001). In comparison, at the site where an active moderator and QI committee are present, respondents seemed more positive about experiencing a QI focus (73% vs. 30%) and changes to practice (44% vs. 16%).

Conclusion

Despite variation in M&M practice, the same (unmet) expectations existed at both hospitals, indicating that certain challenges may be more universal. M&M was reported to be well-focused on education, and certain aspects (e.g., active moderator, QI committee) seemed beneficial, but expectations were not met for the conference's focus and function for QI. Greater exchange of 'best practices' for M&M may enhance the conference's value for improving surgical care.

Key words: morbidity and mortality conference; continuing education; quality improvement; patient safety.

INTRODUCTION

Morbidity and Mortality conferences (M&M) are an established and honored practice in surgery, aiming to improve surgical care through case-based learning.[1–3] M&M practice is specifically related to the ACGME core competencies 'practice-based learning' and 'systems-based practice', but ultimately has the potential to address all six core competencies.[4–6] While both education and quality improvement (QI) are shared goals for most surgical M&M conferences, considerable heterogeneity in M&M practice is apparent in the literature.[1–3,6–13]

M&M practice has been categorized in three domains, including 'goals', 'structure' (e.g., frequency and participants) and 'process/content' (e.g., case selection, presentation and discussion)[5–7] , which have been discussed in various studies. However, fewer than half of all surgical M&M studies included in a recent systematic review of the M&M literature,[7] discussed all domains. Together with the absence of consensus on a best practice for M&M, the limited exchange of practices poses challenges for institutions seeking a format that best fits the local context and is still effective to drive learning and improvement. Variation in M&M practice may to some extent be appropriate to account for contextual differences and to meet local needs. In any case, this variation offers an opportunity to share and learn from each other's (best) practices.

This study sought to evaluate all domains for surgical M&M practice in relation to participants' perspectives at two hospitals with different formats for surgical M&M. A mixed methods approach was used, including local observations and surveys of participants' expectations and experiences of M&M. We hypothesized that comparison of the different formats would reveal different strengths and challenges, but that participants' expectations would be more similar. The aim of this study thus was to compare practices and the extent to which expectations matched experiences in order to learn from each other's strengths and challenges.

METHODS

Design and setting

This mixed methods study assessed M&M practices of the surgical departments of tertiary teaching hospitals Brigham and Women's Hospital (Boston, USA) (BWH; Hospital 1) and Leiden University Medical Center (Leiden, the Netherlands) (LUMC; Hospital 2). Both departments have a long tradition of surgical M&M and seek to continuously improve their practice, but have different formats, which allows for comparison and exchange of practices. Just as surgical M&M practice is thought to have emerged in the early 20th century in the USA,[2] so too is it considered common practice in the Netherlands for over a century. In prior publications, both departments have described specific aspects of their practices, such as special M&M conferences at the beginning of the curriculum at BWH[14] and routine doctor-

driven adverse outcome reporting used for M&M at LUMC since 1997.[15] Both the ACGME and the Dutch Central College of Medical Specialists mandate residency programs to organize M&M conferences.[16,17] While the institutions are of similar size (BWH: 793 beds; LUMC: 882 beds), the BWH Department of Surgery includes more and larger-sized surgical divisions that participate in the surgical M&M (Appendix 1).

For the qualitative part of this study, M&M conferences were observed by a single observer (MSdV) at both sites, which resulted in written descriptions that were presented to local M&M leaders for verification. Observations were guided by key elements of M&M practice identified through review of the literature and preceding interviews with involved clinicians at both centers. To quantitatively assess expectations and experiences of M&M, identical anonymous surveys (Table 1) were distributed at both sites. At Hospital 1, printed surveys were distributed, after verbal instructions, among all participants (n=80) at a regular surgical M&M conference without prior announcements. Surgical attendings, residents and physician assistants of Hospital 2 (n=55) were invited per email to fill out the survey online (SurveyMonkey; in Dutch) and reminders were sent after 1 and 2 weeks. Survey design was based on the observations and key elements found in the literature and included six statements covering the three domains of M&M practice: goals (focus of M&M[7]), structure (mandatory presence[6,12]) and process/content (blame free environment [2,8] and changes to individual practices[8,18]). Expectations and experiences were measured on 5-point Likert scales (0-4), ranging from 'strongly disagree' to 'strongly agree' and 'never (±0%)' to 'every time (±100%)'(Table 1). A 5-point scale was used to provide respondents with a neutral response category (2),

Table 1. Survey assessing expectations and experiences of M&M practice.

	Expectations (how much it *should be*)	**Experience** (how much it *is* currently)[1]
1. The primary focus of M&M is education.	strongly disagree - disagree - neutral - agree - strongly agree	never - rarely - sometimes - often - every time
2. The primary focus of M&M is quality improvement.	strongly disagree - disagree - neutral - agree - strongly agree	never - rarely - sometimes - often - every time
3. M&M is free of 'shame and blame'.	strongly disagree - disagree - neutral - agree - strongly agree	never - rarely - sometimes - often - every time
4. M&M attendance is mandatory for attendings.	strongly disagree - disagree - neutral - agree - strongly agree	never - rarely - sometimes - often - every time
5. M&M attendance is mandatory for residents.	strongly disagree - disagree - neutral - agree - strongly agree	never - rarely - sometimes - often - every time
6. M&M leads to changes to my clinical practice.	strongly disagree - disagree - neutral - agree - strongly agree	never - rarely - sometimes - often - every time
A. What is a key factor for success of your M&M conference?		
B. Suggest one idea that, if implemented, would be most likely to improve the quality of your M&M conference.		
My current position is: attending surgeon - surgical fellow/trainee - physician assistant - medical student - nurse - other.		

[1] The following explanation was provided below this caption: 'never ±0%, rarely ±25%, sometimes ±50%, often ±75%, every time ±100%

but also with more gradations of (dis)agreement (0 and 1; 3 and 4), to prevent tendencies to over-select the center of the scale to avoid voicing extreme opinions (central tendency bias), or tendencies to disproportionately select extreme categories (extreme response styles)[19]. Two open-ended questions asked participants to identify a key factor of success of their conference and to suggest an idea most likely to improve its quality. Ethical approval was obtained from the Institutional Review Board (#2016P001807) in the American hospital, and was not required for this type of study under Dutch law.

Analyses

Characteristics of local M&M practices were compared across the three domains (i.e., goals, structure, process/content).[5–7] Positive and negative response categories for expectations and experiences were clustered (i.e., 0 and 1; 3 and 4) without changing the valence (i.e., negative, neutral or positive) to allow for statistical comparison. This resulted in 3-point scales for expectations (1: (strongly) disagree; 2: neutral; 3: (strongly) agree)) and experiences (1: (less than) rarely; 2: sometimes; 3: (more than) often), which were also used to visualize the survey data. Proportions of participants reporting to expect (i.e., (strongly) agree)) and experience (i.e., (more than) often) were compared per statement using McNemar's test for paired data (i.e., % expected vs. % experienced). Missing values were excluded. A statistically significant difference between expectations and experiences reported for a statement *within* a hospital, was defined as an unmet expectation. Responses of attendings were compared with those of others using the Chi-square test or Fisher's Exact test if expected count was less than five. Statistical analyses were conducted using SPSS software (version 23, IBM, SPSS Inc., Chicago, IL, USA).

RESULTS

Characteristics of M&M practices are compared across three domains in Table 2, and main similarities and differences will be discussed below. Additional details are presented in Appendix 1.

Similarities of M&M practices

Education is the overarching goal of surgical M&M at both institutions. Additional goals include identifying QI opportunities, and longitudinal education on patient safety (Table 2). M&M conferences are organized (bi)weekly with a duration of one hour. Surgical residents are required to attend M&M, and faculty attendance is encouraged. To enhance attendance, both hospitals have blocked time for M&M in clinic and (elective) operating schedules, and sign-in sheets are used to further promote this. Surgeons that have been involved in cases are expected to be actively involved in the preparation and to be present during the presentation

of the case. Residents prepare and perform M&M case presentations, guided by attending supervisors, fixed presentation formats and projected slides. Formal systems to track progress and effect of derived actions for QI are lacking, which is recognized as an important future goal at both hospitals.

Differences of M&M practices

Case collection occurs through manual reporting at Hospital 1. At Hospital 2, routine adverse event reporting, integrated into electronic health records, compiles an electronic list of all potential cases. Cases are selected by the moderator at Hospital 1, who then invites the involved residents to present the cases at M&M. Residents at Hospital 2 are scheduled to present at M&M and may select a case to present regardless of their involvement (Table 2). Participants are offered continuing medical education (CME) credits at Hospital 1 only. The single moderator at Hospital 1 has an active role, contributing to time efficiency (3 cases per one-hour conference) and interactivity of the discussion among participants seated in rows (i.e., theater style). There is less active intervention by moderators of Hospital 2, where moderators alternate each conference, and a less tight time schedule (1 case per one-hour conference) leaves more time for discussion with a smaller audience, all seated around a table. Hospital 1 has a dedicated Surgical Quality Improvement Committee, of which many members are present at M&M, with the capacity to identify proposed ideas and assign them to people for implementation. There is no such committee at Hospital 2, where action items are spontaneously and informally assigned to participants.

Survey

The survey was completed by 90 respondents (Hospital 1: n=53, response: 66%; Hospital 2: n=37, response: 67%), most of which were attendings, followed by residents (Table 3).

Similarities of expectations and experiences of M&M

Similar expectations were expressed by respondents of both hospitals. On average, 9 out of 10 participants (strongly) agreed that the surveyed items *should be* part of M&M (Hospital 1: 90% [79-98%]; Hospital 2: 89% [78-100%]) (Figure 1-2). Both a focus on education and a focus on QI were expected (Hospital 1: 98% vs. 93%; Hospital 2: 93% vs. 78%). Most respondents expected that M&M would change their clinical practice (80%/88%) (Figure 1-2). At both sites, just as many respondents expected mandatory attendance for attendings as did for residents (Hospital 1: both 94%; Hospital 2: both 87%).

Reported experiences also showed many similarities. The same items were least often experienced, including mandatory attendance for attendings (Hospital 1: 43%; Hospital 2: 24%) and changes to practice (Hospital 1: 44%; Hospital 2: 16%) (Figure 1-2). At both sites, 3 out of 10 respondents reported to experience an M&M free of 'shame and blame' sometimes or rarely (none reported 'never'), which included attendings as well as residents (Figure 1-2).

Table 2. Comparison of surgical M&M practices of two hospitals across three domains for M&M practice.

	Hospital 1	Hospital 2
Goals	Education (both individual/departmental) to improve quality of care	
Structure		
Frequency	Once every week (7 a.m.)	Once every 2 weeks (4 p.m.)
Location	Same auditorium	Alternating meeting rooms
Cases/duration	3 cases/60 min	1 case/45-60 min
Clinical activities	No elective surgeries or outpatient clinic appointments planned	
Participants	Faculty, residents, PAs, nurses, students Seated in rows (theater style), some standing	Faculty, residents, PAs, students Round-table setting, all sitting
Attendance	Required for residents, encouraged for attendings Sign-in sheets (CME credits)	Required for residents, encouraged for attendings Sign-in sheets (no credits)
Presenter	Senior resident or fellow involved in case	Resident scheduled to present at M&M
	Attending surgeon as supervisor	
Moderator	Staff surgeon (same individual); active role	Staff surgeon (alternating); less active role
Process/content		
Case reporting	Weekly report by most senior resident/fellow on each service (email to Education Office)	Routine adverse event reporting in EHR
Case selection	Moderator selects from cases reported	Scheduled residents select with supervisor, using case list in EHR/own experience
Presentations	3 x 15-min presentations with projected slides	1x 25 min presentation with projected slides
	Fixed presentation format, incl. literature review, local data and classifications systems for structured analyses (e.g., Clavien-Dindo classification).	
Discussions	3 x 5-min discussions with interactive text-polling	1 x 20-40 min discussion
Assistance	Audio visual services staff present Breakfast and beverages provided	Snacks and beverages provided
Actions plans	Quality Committee (present at M&M, also to present results)	Spontaneously/informally assigned to participant(s)
Repositories	Digital repository for presentations (slides)	
Follow-up/ Feedback	No formal system to follow-up on plans or feedback on effect	

PA, Physician Assistant. *CME*, Continuing Medical Education

Unmet expectations were identified within hospitals, with the following items being significantly more often expected than experienced: a focus on QI (Hospital 1: 98% vs. 73%; P<.001) (Hospital 2: 92% vs. 30%; P<.001), mandatory attendance for attendings (Hospital 1: 94% vs. 43%; P=.004) (Hospital 2: 87% vs. 24%; P<.001) and resulting changes to clinical practice (Hospital 1: 80% vs. 44%; P<.001) (Hospital 2: 88% vs. 16%; P<.001). Reported success factors could be grouped into 8 and 10 categories at both hospitals respectively, of which 6 overlapped, including: review of literature/data; discussion quality; educational value/focus; attendance (mandatory); organization/format and constructive environment (Table 3).

Table 3. Respondent characteristics and reported success factors and ideas for improvement.[1]

		Hosp. 1 n (%)	Hosp. 2 n (%)
Respondents' current position	Attendings	20 (38)	20 (54)
	Residents	12 (23)	14 (38)
	Physician Assistant	3 (6)	3 (8)
	Medical Student	12 (23)	-
	Missing	6 (11)	-
	total	53	37
	response rate (%)[2]	(66%)	(67%)
Key factors for success[3]	Review of literature/data	9 (24)	1 (3)
	Discussion quality	5 (14)	11 (28)
	Presentation quality	5 (14)	-
	Educational value/focus	4 (11)	3 (8)
	Attendance (mandatory)	4 (11)	3 (8)
	Moderator quality	3 (8)	-
	Organization/format	3 (8)	3 (8)
	Constructive environment	2 (5)	1 (3)
	Regularity	-	5 (13)
	Limited number of cases	-	3 (8)
	Fixed presentation format	-	1 (3)
	Focus on improvement	-	3 (8)
	total	37	40
Suggestions for improvement[4]	Increased faculty attendance	4 (17)	-
	Bigger room	4 (17)	-
	Improve case selection	2 (8)	4 (12)
	Improve communications	2 (8)	-
	System-level improvements	2 (8)	-
	Stop interactive polling	2 (8)	-
	Track/feedback improvements	1 (4)	6 (18)
	Subspecialty M&M instead	-	5 (15)
	Stronger focus on improvement	-	5 (15)
	More decision-making details	-	2 (6)
	Strive for completeness		2 (6)
	total	24	34

Hosp., Hospital (i.e., surgical departments of 1: Brigham and Women's Hospital, Boston, USA, and 2: Leiden University Medical Center, Leiden, the Netherlands).

[1] Column percentages. Some respondents reported two success factors or ideas for improvement.

[2] Hospital 1: 53 of 80 (66%); Hospital 2: 37 of 55 (67%).

[3] Reported by 29 (55%) and 31 (84%) of respondents at Hospital 1 and 2 respectively. Other (n=1) reported factors include at Hospital 1: 'opportunity for discussion between different specialties present'; fixed presentation format'; at Hospital 2: 'timing'; 'relevance'; 'insight in complex cases'; 'residents' input'; 'faculty supervisor'; 'discuss many cases'; and at both: 'different specialties present.'

[4] Reported by 22 (42%) and 29 (78%) of respondents at Hospital 1 and 2 respectively. Other (n=1) suggestions include at Hospital 1: 'rotate moderator'; 'have a senior attending comment in addition to residents comments on causality of their complication'; 'point/counterpoint topics'; 'implementable QA plan discussion'; 'call in remotely'; 'multi-institutional participation'; 'change to later time'; and at Hospital 2: 'better support'; 'attendance'; 'more frequent'; 'documentation'; 'more questions to audience'; 'presenters based on involvement'; 'more literature'; 'merge with other mortality case presentations'; 'more general themes'.

Differences between expectations and experiences of M&M

Gaps between expectations and experiences seemed larger and more common at Hospital 2, where unmet expectations were identified for two additional items, including absence of shame and blame and mandatory attendance for residents (Figure 1-2). While responses of attendings did not differ from other respondents at Hospital 1, attendings at Hospital 2 less often expected a focus on education (65% vs. 94%; P=.048) and less often experienced a focus on QI (10% vs. 53% ; P=.004) compared to residents or physician assistants.

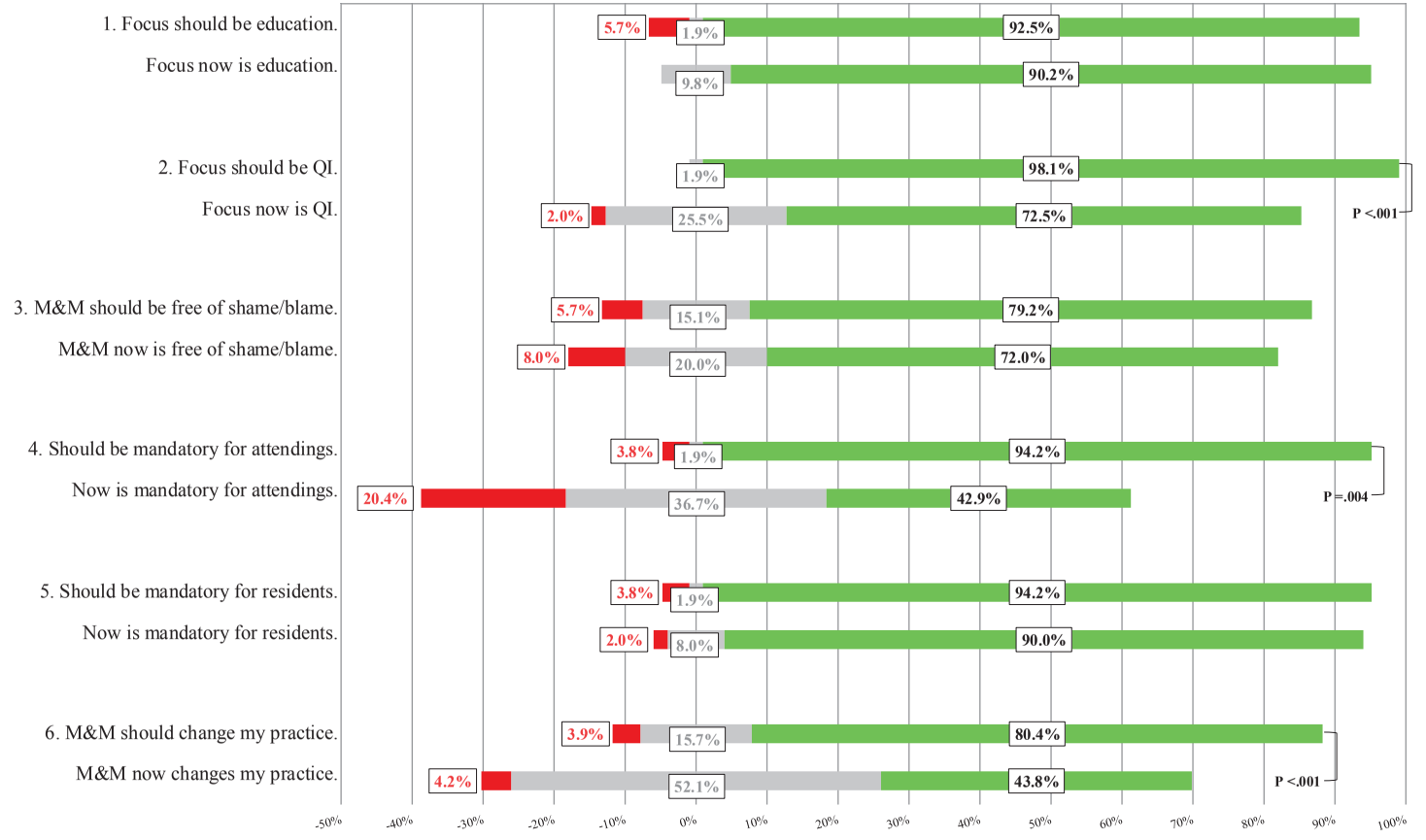
Most frequently reported success factors were 'review of literature/data' at Hospital 1 (24%) and 'discussion quality' at Hospital 2 (28%) (Table 3). Most frequently reported suggestions for improvement were increased faculty attendance (17%) and a bigger room (17%) at Hospital 1, while suggestions at Hospital 2 mostly concerned tracking of and feedback on improvements (18%), subspecialty instead of departmental M&M (15%) and a stronger focus on QI (15%).

DISCUSSION

This study used a mixed methods approach to evaluate surgical M&M practices of two hospitals with a long tradition of M&M. The M&M practices shared similar goals, but differed in various aspects on the domains of structure and process/content. Despite these differences, the same expectations for M&M were reported at both sites: most participants expected M&M to be focused on both education and QI, to be blame-free, mandatory for both residents and attendings, and to lead to changes to one's clinical practice. However, at both hospitals, significantly fewer participants experienced: a focus on QI; mandatory faculty attendance; and changes to clinical practice.

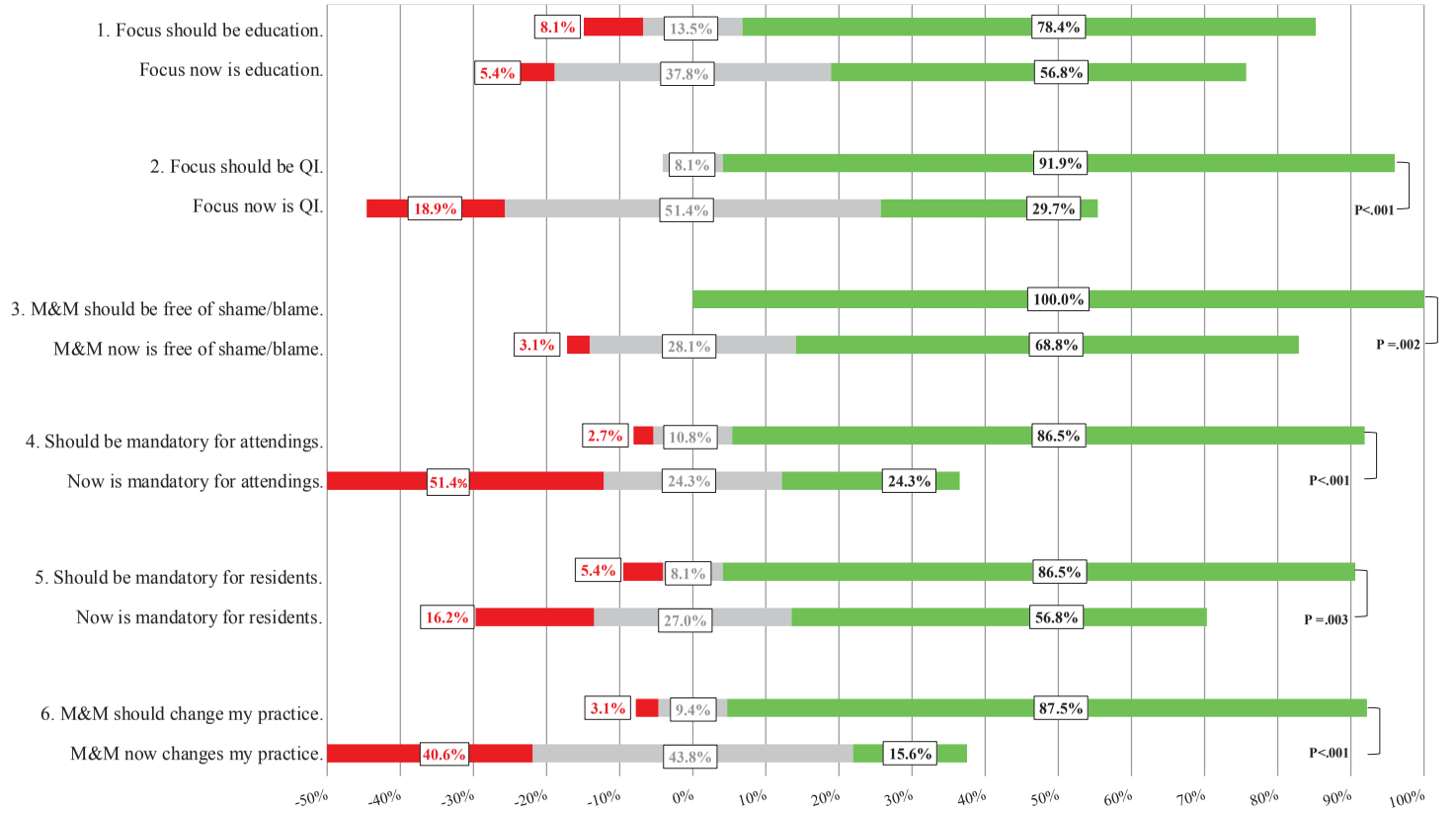
While surveys about M&M have been published before,[10,20,21] no prior studies have related experiences and (unmet) expectations for key aspects of M&M to observed differences in practice, and descriptions of all key domains of M&M practice are only rarely covered (i.e., goals, structure, process/content).[7] This mixed methods approach allowed exploring differences and similarities in various aspects of M&M practice as well as participants' perceptions.

Figure 1. Survey responses from Hospital 1 with expectations depicted first and experiences second per statement (full statements in Table 1).



Red, grey and green bars represent negative, neutral and positive responses respectively. Significant differences between proportions are supplemented with P-values.

Figure 2. Survey responses from Hospital 2 with expectations depicted first and experiences second per statement (full statements in Table 1).



Red, grey and green bars represent negative, neutral and positive responses respectively. Significant differences between proportions are supplemented with P-values.

Shared challenges

Most participants reported that M&M was well-focused on education, but expectations were not met for its QI function, in terms of a focus on QI and subsequent changes to clinical practice. This might be related to the observed lack of formal systems for follow-up of QI plans at both hospitals, which might hamper 'closing the quality loop' on the individual and system level.[5,13] Recording and monitoring of plans is associated with increased effectiveness for QI, but often not part of M&M,[22,23] nor of many other practices for learning and improving in healthcare (e.g., incident reporting), which often lack attention for dissemination, follow-up and feedback.[13,24–27] Dedicated task groups or committees, as used at Hospital 1, facilitate translating discussions into actual improvements.[4,9,13,28] This may explain why Hospital 1 respondents more often experienced QI aspects than colleagues at Hospital 2, where such a committee is absent (QI focus: 73% vs. 30%; changes: 44% vs. 16%). However, most participants still expected more from M&M's function for QI, indicating that both departments could benefit from dedicating time at M&M to tracking prior QI initiatives. To allow time for this form of follow-up, programs could consider limiting the number of cases per conference (as in Hospital 2) or time spent per presentation or discussion (as in Hospital 1).

Similar to many other institutions, both Hospital 1 and 2 only formally require residents to attend. This study revealed, however, that M&M participants also expect mandatory faculty attendance. Unmet expectations for M&M attendance might be related to unmet expectations for the QI function of M&M. Lack of feedback on the changes that result from ideas participants helped generate at M&M, might negatively impact belief in the value of the conference and hence motivation to attend.[5,13] A prior study revealed that motivations to participate in M&M mostly related to individual or team-based improvement.[21] When M&M proves useful to its participants, this will likely act as a positive feedback loop[28] as well as improve attendance rates.[8,10] The importance of faculty attendance at M&M has been highlighted in prior studies,[5,6,22] but actionable recommendations to promote attendance rates are lacking. The present study suggests that sign-in sheets and blocking time in clinic and surgery schedules, used at both hospitals to enhance attendance, may not provide enough incentives, as respondents still supported the statement that faculty attendance should be mandatory. While the expectation of faculty attendance could be made more explicit, feasibility should be carefully examined, as it may interfere with other clinical duties, such as appointments at remote locations of the hospital.

Strengths of different formats

Gaps between expectations and experiences seemed larger at Hospital 2 and were more frequent. Based on our observations, we partly attribute this to the more active role of the moderator in Hospital 1, often considered a key feature of success for M&M.[6,21,22] As unmet expectations for mandatory attendance for residents were only present at Hospital 2, offering

educational points such as (a local equivalent to) CME credits, as practiced at the Hospital 1, might provide an additional incentive.

Reported success factors were mostly linked to presentations at Hospital 1, and to discussions at Hospital 2, which might also be related to differences in M&M formats. M&M conferences at Hospital 1 include three case presentations, and presenters are always acquainted with cases. Hospital 2, however, allows more time for discussion by only discussing a single case, and uses a round-table setting, which may further increase the focus on the discussion. An optimum balance should be found between time devoted to presentations and discussions, but there is no decisive evidence favoring a certain number of cases.[6,7,10,23]

Many studies show benefits of using visual aids and standardized formats that include literature and data (e.g., National Surgical Quality Improvement Program).[12,13,21,23,29] These were used at both sites and might have contributed to the positive results for the educational focus of M&M. Despite that discussion quality was often reported as success factor and despite practical differences (e.g., moderator style, table setting), still 3 out of 10 respondents at both sites reported to only 'sometimes' or 'rarely' experience a conference free of shame and blame, highlighting the difficult and delicate nature of M&M practice.[2,8,20]

Study strengths and limitations

Strengths of this study include its multi-institutional, multi-national and mixed-methods design with good survey response rates, enabling quantitative and qualitative evaluations of practices for surgical M&M. This study also has important limitations. First, it remains unclear to what extent the findings are generalizable to other institutions. The provided descriptions of M&M practices may help relate the findings to other specific settings (e.g., smaller sized departments may bear more resemblance to Hospital 2). The small survey was deliberately chosen to enhance feasibility, but limits the richness of information. Survey response differences *between* hospitals must be interpreted with caution. The risk of socially desirable answers may be greater at Hospital 1 as a survey in a conference room may feel less anonymous than an online survey, used at Hospital 2. The survey at Hospital 1 was not announced in advance, which strengthens our belief that attendees at this particular conference were an accurate representation of those who usually attend. However, cultural differences may have affected responses to Likert scales as the Dutch are known to express strong opinions,[30] while Americans may have a stronger tendency to focus on positive rather than negative aspects.[31] For these reasons, the two sites were only compared using descriptive statistics and unmet expectations that were identified *within* hospitals.

Future directions

This study suggests additional leads to achieve further gains in M&M practice. To adapt this traditional practice for surgical education to contemporary needs, M&M should be used as a platform for improvement, which further allows M&M to be linked to other ACGME require-

ments such as education on patient safety and QI strategies.[13,32] To guide efforts towards best practices for M&M, future research should disseminate actionable recommendations on how to best organize M&M with a noticeable QI focus and effect, implement routine tracking of progress and effect of prior actions, and how to achieve (mandatory) faculty attendance.

CONCLUSIONS

Despite well-known practice variation in surgical M&M practice, challenges to meet certain expectations for M&M may be more universal. While only residents were required to attend conferences, M&M participants expected mandatory faculty attendance as well. Expectations for the educational focus of M&M were met, and certain features of M&M seemed beneficial, but expectations were not met for the conference's focus and function for QI at both sites. Greater exchange of best practices could guide improving M&M's function for QI, which includes effecting, as well as demonstrating, its value for improving surgical care.

REFERENCES

1. Gordon L. *Gordon's Guide to the Surgical Morbidity and Mortality Conference.* Philadelphia, PA: Hanley and Belfus; 1994.
2. Orlander JD, Barber TW, Fincke BG. The morbidity and mortality conference: the delicate nature of learning from error. *Acad Med*. 2002;77:1001-1006. doi:10.1097/00001888-200210000-00011.
3. Pierluissi E, Fischer M, Campbell A, Landefeld CS. Discussion of medical errors in morbidity and mortality conferences. *JAMA*. 2003;290:2838-2842. doi:10.1001/jama.290.21.2838.
4. Kauffmann RM, Landman MP, Shelton J, et al. The Use of a Multidisciplinary Morbidity and Mortality Conference to Incorporate ACGME General Competencies. *J Surg Educ*. 2011;68:303-308. doi:10.1016/j.jsurg.2011.02.002.
5. Flynn-O'brien KT, Mandell SP, Van Eaton E, et al. Surgery and Medicine Residents' Perspectives of Morbidity and Mortality Conference: An Interdisciplinary Approach to Improve ACGME Core Competency Compliance. *J Surg Educ*. 2015;72:e258-e266. doi:10.1016/j.jsurg.2015.05.015.
6. Aboumatar H, Blackledge C, Dickson C, et al. A Descriptive Study of Morbidity and Mortality Conferences and Their Conformity to Medical Incident Analysis Models: Results of the Morbidity and Mortality Conference Improvement Study, Phase 1. *Am J Med Qual*. 2007;22:232-238.
7. Xiong X, Johnson T, Jayaraman D, et al. At the Crossroad with Morbidity and Mortality Conferences: Lessons Learned through a Narrative Systematic Review. *Can J Gastroenterol Hepatol*. 2016;2016:1-11. doi:10.1155/2016/7679196.
8. Bechtold ML, Scott S, Dellsperger KC, et al. Educational quality improvement report: outcomes from a revised morbidity and mortality format that emphasised patient safety. *Postgrad Med J*. 2008;84:211-216. doi:10.1136/qshc.2006.021139.
9. Deis JN, Smith KM, Warren MD, et al. *Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement*. Agency for Healthcare Research and Quality (US); 2008. http://www.ncbi.nlm.nih.gov/pubmed/21249895 (Accessed 15 June 2016).
10. Gore DC. National survey of surgical morbidity and mortality conferences. *Am J Surg*. 2006;191:708-714. doi:10.1016/j.amjsurg.2006.01.029.
11. Hamby LS, Birkmeyer JD, Birkmeyer C, et al. Using Prospective Outcomes Data to Improve Morbidity and Mortality Conferences. *Curr Surg*. 2000;57:384-388.
12. Mitchell EL, Lee DY, Arora S, et al. Improving the Quality of the Surgical Morbidity and Mortality Conference. *Acad Med*. 2013;88:824-830. doi:10.1097/ACM.0b013e31828f87fe.
13. Sacks GD, Lawson EH, Tillou A, et al. Morbidity and Mortality Conference 2.0. *Ann Surg*. 2015;262:228-229. doi:10.1097/SLA.0000000000001268.
14. De Vos MS, Smith AD, Shimizu N, Whang EE. Surgical Quality Improvement Book Chapter 5 : Morbidity and Mortality Conference : a Weekly Conference Designed to Improve Surgical Quality. 2013. Available at: http://www.brighamandwomens.org/ Departments_and_Services/surgery/qiChapter5.aspx?sub=0. (Accessed 7 June 2017).
15. Kievit J, Krukerink M, Marang-van de Mheen PJ. Surgical adverse outcome reporting as part of routine clinical care. *Qual Saf Health Care*. 2010;19:e20. doi:10.1136/qshc.2008.027458.
16. *ACGME Program Requirements for Graduate Medical Education in General Surgery*. Chicago, IL https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/440_general_surgery_2016.pdf (Accessed 17 October 2016).
17. *Kaderbesluit CCMS (Dutch)*; 2014. http://knmg.artsennet.nl/Opleiding-en-herregistratie/CGS/Regelgeving/Huidigeregelgeving.htm (Accessed 17 October 2016).

18. Calder LA, Kwok ESH, Cwinn A, et al. Enhancing the quality of morbidity and mortality rounds: The Ottawa M&M model. *Acad Emerg Med*. 2014;21:314-321. doi:10.1111/acem.12330.
19. Weijters B, Cabooter C, Schillewaert N. The Effect of Rating Scale Format on Response Styles: The Number of Response Categories and Response Category Labels. *Int J Res Mark*. 2010;27:236-247. doi:10.1016/j.ijresmar.2010.02.004.
20. Harbison SP, Regehr G. Faculty and resident opinions regarding the role of morbidity and mortality conference. *Am J Surg*. 1999;177:136-139. doi:10.1016/S0002-9610(98)00319-5.
21. Lecoanet A, Vidal-Trecan G, Prate F, et al. Assessment of the contribution of morbidity and mortality conferences to quality and safety improvement: a survey of participants' perceptions. *BMC Health Serv Res*. 2016;16:176. doi:10.1186/s12913-016-1431-5.
22. François P, Prate F, Vidal-Trecan G, et al. Characteristics of morbidity and mortality conferences associated with the implementation of patient safety improvement initiatives, an observational study. *BMC Health Serv Res*. 2016. doi:10.1186/s12913-016-1279-8.
23. Bal G, Sellier E, Tchouda SD, et al. Improving quality of care and patient safety through morbidity and mortality conferences. *J Healthc Qual*. 2014;36:29-36.
24. Macrae C. The problem with incident reporting. *BMJ Qual Saf*. 2016;25:71-75. doi:10.1136/bmjqs-2015-004732.
25. Cooke DL, Dunscombe PB, Lee RC. Using a survey of incident reporting and learning practices to improve organisational learning at a cancer care centre. *Qual Saf Heal Care*. 2007;16:342-348. doi:10.1136/qshc.2006.018754.
26. Ginsburg LR, Chuang YT, Norton PG, et al. Development of a measure of patient safety event learning responses: Patient safety and public health. *Health Serv Res*. 2009;44:2123-2147. doi:10.1111/j.1475-6773.2009.01021.x.
27. Vincent C. Understanding and Responding to Adverse Events. *N Engl J Med*. 2003;348:1051-1056.
28. Kwok ESH, Calder LA, Barlow-Krelina E, et al. Implementation of a structured hospital-wide morbidity and mortality rounds model. *BMJ Qual Saf* 2017;26:439-448. doi:10.1136/bmjqs-2016-005459.
29. Widyahening IS, van der Heijden GJMG, Moy FM, et al. Direct short-term effects of EBP teaching: change in knowledge, not in attitude; a cross-cultural comparison among students from European and Asian medical schools. *Med Educ Online*. 2012;17:19623. doi:10.3402/meo.v17i0.19623.
30. Koopman-Holm B, Tsai JL. Focusing on the Negative: Cultural Differences in Expressions of Sympathy. *J Pers Soc Physchol*. 2014;107:1092-1115. doi:10.1037/a0037684.Focusing.
31. Kim MJ, Fleming FJ, Peters JH, et al. Improvement in educational effectiveness of morbidity and mortality conferences with structured presentation and analysis of complications. *J Surg Educ*. 2010;67:400-405. doi:10.1016/j.jsurg.2010.04.005.
32. Nasca T, Philibert I, Brigham T, et al. The Next GME Accreditation System - Rationale and Benefits. *N Engl J Med*. 2012;366:1051-1056.

APPENDIX

Appendix 1. Descriptions of surgical M&M practices at Brigham and Women's Hospital (BWH) (Hospital 1) and Leiden University Medical Center (LUMC) (Hospital 2).

Divisions

At Hospital 1, the surgical M&M conference usually includes the following divisions: colorectal, vascular, bariatric, trauma, transplant, and minimally invasive surgery, and surgical oncology, with a total of 156 attendings and 88 residents. Attendance data reveal that 58 of these attendings have gone to at least one M&M conference last year, of which a group of 38 regularly. Conferences usually have around 80 participants. Other divisions attend intermittently and not routinely, including cardiac surgery, thoracic surgery, plastic surgery, orthopedic surgery, urology, and ENT. At hospital 2, surgical M&M includes general, colorectal, vascular, trauma, surgical oncology, pediatric and transplant surgery with a total of 25 attendings, 5 physician assistants, and approximately 25 residents, among which all are regular participants of their M&M conference.

Structure

The conferences are planned at the same time every week (Hospital 1) or two weeks (Hospital 2). For the role of moderator, Hospital 1 has designated a single attending surgeon, while all faculty members alternately fulfill this role at Hospital 2. This role is also carried out differently: the Hospital 1 moderator plays a notably more active role in leading the discussion and chairing the meeting compared to moderators at Hospital 2 as he more actively intervenes (using a microphone) to promote interactivity as well as time efficiency.

Case selection

Cases with potential for M&M are reported each week by the senior-most resident or fellow on each service at Hospital 1 via emails to the Surgical Education Office. Their moderator then selects cases for M&M from the list of reported cases. At Hospital 2, residents and physician assistants, under faculty supervision, routinely report all adverse events during hospitalization or at patient discharge into an system for adverse event reporting integrated into the electronic health record (EHR) software. This enables automated selection of cases with severe (i.e., leading to reoperation, irreversible harm or death) or more than two adverse events resulting in a case list with potential cases for M&M. The residents scheduled to present at M&M may select a case, using the case list compiled by the EHR-integrated reporting system or drawing from their own experience, in consultation with the attending assigned as supervisor. Both programs expect the involved attending to be present during presentation of their case. Sometimes conflicts do emerge (e.g., emergency surgery), but presentations are

usually rescheduled if that happens. Involved attendings are also involved during preparation, as resident presenters are supervised by the attending involved in the case or approach him/her to discuss case details in advance of M&M.

Presentations

All presentations are supported by projected slides, following a fixed format that includes a summary of the case followed by a review of literature, published and local data (e.g., using NSQIP Surgical Risk Calculator or local registries). Hospital 1 requires residents to propose a QI project that could address the problem covered in the case. Both hospitals use classification systems for categorization of complications reflecting consequences for the patient: Hospital 1 uses the well-known Clavien-Dindo classification (Dindo D, Demartines N Clavien P-A. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004;240(2):205-13), and Hospital 2 uses the classification of Association of Surgeons of the Netherlands ('NVvH')[15] with four severity levels reflecting consequences for patients, including I: recovery without (re)operation; II: recovery after (re)operation; III (potential) irreversible harm; IV: death. At Hospital 1, the discussion is supplemented (since 6/2015) by an interactive polling system, where the audience members use their cell phones to vote on which factor (e.g.,, patient, clinician, team, systems, or current medical technology limitations) was the primary contributor to the adverse outcome.

To provide a reference for M&M-derived knowledge, both departments store all M&M presentations in a digital repository. The EHR-embedded system for adverse event reporting at Hospital 2, also allows to log lessons for future patient care that derive from M&M, but these data are not used to track progress of effects of actions. Many members of the dedicated Surgical Quality Improvement Committee, used at Hospital 1, are present at M&M and results of QI initiatives are often presented at subsequent conferences.

Chapter 3

Barriers and facilitators to learn and improve through morbidity and mortality conferences: a qualitative study

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ABSTRACT

Objective

To explore barriers and facilitators to successful morbidity and mortality conferences (M&M), driving learning and improvement.

Design

This is a qualitative study with semistructured interviews. Inductive, thematic content analysis was used to identify barriers and facilitators, which were structured across a pre-existing framework for change in healthcare.

Setting

Dutch academic surgical department with a long tradition of M&M.

Participants

An interview sample of surgeons, residents and physician assistants (n=12).

Results

A total of 57 barriers and facilitators to successful M&M, covering 17 themes, varying from 'case type' to 'leadership', were perceived by surgical staff. While some factors related to M&M organisation, others concerned individual or social aspects. Eight factors, of which four were at the social level, had simultaneous positive and negative effects (e.g.,'hierarchy' and 'team spirit'). Mediating pathways for M&M success were found to relate to available *information*; staff *motivation*; and *realisation* processes.

Conclusion

This study provides leads for improvement of M&M practice, as well as for further research on key elements of successful M&M. Various factors were perceived to affect M&M success, of which many were individual and social rather than organisational factors, affecting information and realisation processes but also staff motivation. Based on these findings, practical recommendations were formulated to guide efforts towards best practices for M&M.

Key words: morbidity and mortality conferences; quality improvement; patient safety; continuing education; barriers and facilitators; professionals; providers.

INTRODUCTION

The morbidity and mortality conference (M&M) is a deep-rooted tradition in surgery, adopted by many other medical specialties, aiming to serve both educational and quality improvement (QI) purposes.[1,2] M&M additionally provides opportunities to teach principles of patient safety and QI, which are current requirements for residency education.[3–5] Despite similar objectives, significant variation exists in M&M practice.[1,3] Case presentations and discussions may highlight important learning points, but implementation and follow-up often receive less attention at the conference, which is a known challenge for many improvement practices in health care.[5–9]

M&M practice variation is likely related to the fact that key factors for successful M&M, driving learning and improvement, remain largely unclear. Factors that have been reported include organisational aspects, such as a structured approach to review events,[10,11] using moderators,[2,12–14] and participation of all involved staff, [10,15,16] which were corroborated by survey studies.[3,17–20] Except for the importance of a safe, blame-free environment,[2,12] the impact of non-organisational factors, such as team dynamics, has not been considered. While learning and change theories stipulate that these processes occur at different levels, affected by various factors at the individual and team level,[21–24] it remains unknown to what extent these factors effect learning and improving processes at M&M.

We hypothesized that barriers and facilitators to successful M&M, resulting in learning and improvement, also exist at the individual and social level. To obtain a broad and nuanced understanding of the complexity of factors influencing M&M success, a qualitative approach was used. Qualitative studies have rarely been used to study M&M, but can yield rich insights that may not be revealed by quantitative assessments. The purpose of this study was to enhance understanding of the barriers, facilitators and mediating pathways to successful M&M, driving learning and improvement of clinical practice.

METHODS

A total of 12 semi-structured one-hour interviews were conducted to identify barriers and facilitators for successful M&M. This qualitative approach was chosen as it allows exploring perceptions, and encourages participants to share rich descriptions and in-depth information.[25] The number of 12 interviews was selected because of feasibility and anticipated number needed to reach data saturation, defined as three consecutive interviews without additional themes emerging.[26] Purposive sampling was used to invite participants via telephone or email - varying gender, seniority and surgical subspecialty - to obtain a diversity of viewpoints and hence increase the ability to identify all relevant barriers and facilitators. Standards for reporting qualitative research were used to guide reporting of this study.[27]

All invited agreed to participate, including six attending surgeons, five surgical residents and one physician assistant (PA) (four women; mean local work experience: 7.2 years [range 1-18 years]). All worked at the surgical department of a large academic hospital in the Netherlands (882 beds), covering general, endocrine, vascular, gastrointestinal, paediatric, oncologic, trauma and transplant surgery (all represented in the interview sample). All interviewees had prior experience with M&M practice at other, mostly teaching, hospitals. The department has a long tradition of departmental M&M meetings, which gather all faculty, residents, PAs and medical students to discuss a single case during a 1-hour conference every 2 weeks. More details on the local M&M format can be found in prior publications.[28,29] Cases are selected and presented by residents under faculty supervision (i.e., regardless of their involvement). A single case is presented per meeting with the aid of fixed presentation formats, which is followed by a 20-40 minute discussion led by a moderator.[29]

Prior to the interview, participants were informed about the study objectives and design. Identity of interviewees was kept anonymous to both colleagues and department chiefs to protect confidentiality and promote openness. A topic guide was developed to guide the interviews (Appendix 1). First, participants were asked about their overall opinion on M&M practice and what factors may affect M&M success, defined as a conference that results in learning and improvement. This broad definition was intentionally selected to allow interviewees to freely explore what makes a successful M&M. Interviewees were encouraged to discuss experiences with M&M in both the local and other hospitals (e.g., due to hospital rotation during residency), as well as factors that they expected but never experienced. Further questions related to the perceived effect of factors that are most common in the M&M literature, related to the conference's structure (i.e., attendance, culture) and content (i.e., case selection, presentation, moderation, deriving plans).[3,29] Questions about experiences with the local M&M were used to evoke discussion of generic success factors and barriers (e.g., what illustrates that your M&M is [not] free of shame and blame?)

Each interviewee was interviewed individually in a conference room of a research department in the hospital. Interviews were audiotaped and transcribed in full. Anonymized transcripts were analysed using thematic content analysis with an inductive, data-driven approach, which involved a recursive process of open coding and collocating codes into themes.[30,31] Coding was performed in ATLAS.ti software (GmbH, Berlin, Germany) by the same researcher who individually conducted the interviews (MdV). This researcher has an MD degree and experience in research on M&M,[29,32] but no professional relationship with interviewees as she is currently not involved in clinical work. A second coder, who was a research assistant with qualitative research experience, independently reviewed all coded transcripts for continuity of data interpretation and any miscoded statements, and discussed with the primary coder until consensus was reached. To guide the analysis, emerging themes were structured across six domains of a pre-existing framework for barriers to and incentives for change in healthcare, developed based on various theories and models for implementing

change.[22] Domains included: case (adapted from 'patient'), action (adapted from 'innovation'), individual professional, social context, organisational context, and external context. Frequencies of reported factors were only reported when notably high, low or different between residents and faculty. Factors were assessed for their direction of effect (i.e., facilitator, barrier or both) and their pathways to achieve a successful M&M (i.e., how exactly does this enhance M&M-based learning and improvement?). The mediating pathways for M&M success identified in this study were subsequently assessed for their relation to existing, more general frameworks for improvement in healthcare.[22]

RESULTS

A total of 57 facilitators and barriers for M&M success were reported by interviewed professionals (Table 1). All were reported in at least three interviews, and data saturation was reached at the 10th interview. More facilitators than barriers were reported, with most facilitators at the case level, and most barriers at the organisational level. Many facilitators could also serve as a barrier if absent or insufficient (e.g., motivation), but for eight factors, of which four were at the social level, both positive and negative effects were perceived simultaneously (e.g., hierarchy) (Table 1). Illustrative quotes for all facilitators and barriers are provided in Appendix 2. Facilitators and barriers were grouped into 17 themes, which will be discussed per level of the framework for change in healthcare (Table 1).

Case/action level

The type of case discussed at M&M as well as the type of action items, were reported as influencing factors. Cases and actions dealing with clinically relevant and attractive topics (i.e., high severity/frequency and surgical technical issues) were perceived to increase sense of urgency to bring about change (Table 1).

> "*We like that [surgical technique]. We're all very practical people.*" (#7)

To enhance information transfer, presenters should be skilful, well-prepared and supervised, using fixed presentation formats to cover the case, pertinent literature, surgical skills and involved system-level factors. M&M was also seen as an important opportunity to address soft skills, such as communication or emotional impact. Including local data and trends was perceived to instigate reflection and increase the sense of urgency.

> "*(…) about pneumonia, everyone will be like 'oh no, boring', but if you present a concise plan and numbers and those things, then, I think that'd be very nice, because that concerns everyone.*" (#5)

Table 1. Facilitators and barriers to successful M&M practice, grouped in themes and structured across levels of a framework for achieving change in healthcare.

Theme	*Factor*	*Facilitator* (+)	*Barrier* (–)
I) Case level			
Type of case (1)	Attractive topic	+	
	Clinical relevance	+	
	Value for education/improvement	+	
Information (2)	Include local data	+	
	Literature	+	
	Skills education	+	
	Information from those involved	+	–
	Addressing system factors	+	
	Addressing 'soft skills'	+	
Presentation (3)	Qualified presenter	+	
	Proper preparation	+	
	Proper supervision	+	
	Fixed format	+	
II) Action level			
Type of plan (4)	Attractive topic	+	
	Clinically significant topic	+	
	More disciplines involved		–
	Higher complexity		–
Planning (5)	Explicitly formulated	+	
	Responsibility assigned	+	–
	Time frame determined	+	
	Included in protocols	+	
III) Individual level			
Motivation (6)	Intrinsic motivation	+	
	Interest in specific topic	+	
	Values/beliefs	+	–
	Other priorities/incentives		–
Participation (7)	Personality	+	–
Realisation (8)	Empowerment, control	+	
	Forgetfulness		–
IV) Social level			
Culture (9)	Safe environment	+	
	Team spirit	+	–
	Super specialization		–
Leadership (10)	Reinforcing attendance	+	
	Reinforcing actions	+	
	Hierarchy	+	–
	Exemplary behaviour	+	

Table 1. Facilitators and barriers to successful M&M practice, grouped in themes and structured across levels of a framework for achieving change in healthcare. (continued)

Theme	*Factor*	*Facilitator* (+)	*Barrier* (–)
Participants (11)	Participation of experts	+	
	Interactivity	+	
	Audience composition/size	+	–
	Multidisciplinary participation	+	–
Moderation (12)	Qualified moderator	+	
V) Organisational level			
M&M format (13)	Strong focus on improvement	+	
	M&M in specialist setting	+	
	Communications (before/after)	+	
	Too many cases per meeting		–
	No tracking of actions		–
	No check/feedback on effect		–
Reporting (14)	System for data collection	+	
	Difficult access to data		–
	Lack of feedback from data		–
Staff (15)	Dedicated staff/committee	+	
	Super specialization		–
	Staff turnover		–
	Other/conflicting expectations		–
Time (16)	Overall lack of time		–
	Receiving dedicated time	+	
VI) External level			
Healthcare (17)	Inevitability ('nature')		–
	Benchmarking	+	

Details regarding context and deliberations in cases should be obtained from those involved, but some residents added that (emotional) involvement might also bias judgment and hinder information accuracy.

Overall complexity of proposed actions was perceived as a barrier to implementation and considered to increase with the number of people or disciplines involved. Hence plans should be explicit, including a timeline and person in charge. At the same time, however, top-down task assignment could hinder implementation, referred to as 'mandatory volunteerism'.

> *"If you just send someone off like 'you go do that', that won't work, it has been proven."* (#9)

Individual level

In various ways, professionals perceived 'motivation' as a powerful and important facilitator for M&M, enhancing attendance rates, active participation, and subsequent realisation of actions (Table 1). Motivation was considered to improve when M&M covered topics applicable to one's own practice or field of interest, or when topics were accompanied by a sense of urgency.

Individual personalities were mentioned as potential facilitators as well as barriers, as for example insecurity may hamper speaking up, while other personality traits could be beneficial in that respect. Similarly, personal values and beliefs could enhance or impede motivation to attend, participate and carry out actions. Feedback on actions from prior conferences was considered essential to demonstrate the value of M&M

> "*Did anything change? (…) Feedback needs to improve greatly, otherwise it's so useless.*" (#10)

A barrier was perceived in that staff may prioritize other activities over M&M, such as clinical work or training duties (mostly mentioned by residents) or subspecialty-related activities (mostly mentioned by faculty).

> "*I'm particularly interested in my own service [i.e., subspecialty], those are my patients and my trainees.*" (#6)

Some noted that it should be prevented that M&M is considered a 'chore' as this decreases motivation, but others considered such 'chores' components of professionalism.

> "*(…) some things are chores, but just need to be done.*" (#4)

Social level

The need for a safe environment to allow for an open discussion was often expressed (Table 1). In this respect, a strong sense of team spirit was considered beneficial (e.g., counting on support from peers), but also a potential barrier as one may withhold comments to avoid offending a colleague, referred to as 'back-stabbing' (Appendix 2). Super specialization in surgery was mentioned by all but one interviewee, and considered to have negatively affected team spirit, decreasing interest and motivation for topics outside one's subspecialty.

> *"If you talk about pseudarthrosis, I'm sure no gastro-intestinal or vascular guy really enjoys it."* (#5)

Some suggested that M&M could therefore cover more general topics or increasingly focus on more general aspects, such as communication skills or teamwork involved, as these are shared among different subspecialties.

Leadership was assigned a critical role in harnessing this desired culture through exemplary behaviour and actively lowering barriers to speaking up.

> *"It helps to see that things at times go wrong even for someone you perhaps admire, some expert."* (#11)

Some believed that faculty attendance may set an example to juniors, but others believed that mandatory attendance should be actively reinforced with staff held accountable for absences. All stressed that leadership should check and reinforce progress of M&M-derived actions, and that hierarchy helps in this respect. At the same time, hierarchy may serve as a barrier to an open discussion.

> *"If you really want to promote free speech, then faculty should emphasize that hierarchy is put aside during such a conference."* (#7)

To steer discussions, promoting a safe atmosphere, the use of moderators was considered helpful.

While high attendance rates may serve as a motivator and increase available information and reach, a smaller audience size may better promote a safe and open environment. Similarly, audience composition (i.e., who is present) can both positively and negatively affect the discussion.

> "*You really think about who is involved and try to predict how that person will respond. In some cases, you'll decide: well, I'm not going to do that here.*" (#3)

Specifically, it was considered important to increase interactivity and involve experts or staff who had been involved in the cases, to enhance discussion quality and participant experience. Multidisciplinary participation was considered to provide essential information, but also to potentially negatively affect openness and level of discussions.

> "*Well then there might be some competence differences. Perhaps for some topics it could work, but not in general I'd say.*" (#9)

Organisational/external level

With regards to the M&M format, a strong focus on improvement, and (preceding) communications were considered beneficial. Handling too many cases was mentioned as a potential

barrier, as it may decrease attention and time for discussing opportunities for improvement (Table 1). With regards to the setting, most faculty (4 of 6) advocated for subspecialty rather than departmental M&M, as it would allow discussions to focus on subspecialist topics, which would increase participants' motivation and ability to change processes at their own ward. Moreover, super specialization may currently limit one's ability to attend M&M.

> *"My weeks are overloaded with duties related to my subspecialty (…) An unstoppable phenomenon. The generic conferences suffer from it."* (#4)

Reporting systems were appreciated for their value to collect local data, but lack of feedback was considered a missed opportunity to increase sense of urgency for topics and encourage reporting behaviour. Residents currently perceived a barrier in that it was too labour-intensive and difficult to access local data, while this could provide essential support for case selection, presentations and follow-up. Many also missed systematic follow-up, evaluation and feedback on prior actions at M&M.

> "*A sort of follow-up makes it all more cohesive, of course, it'll give you the feeling that you're all involved in a sort of improvement cycle rather than scattershot.*" (#8)

Lack of continuity due to typical staff turnover in teaching hospitals was considered to hamper (sustaining) improvements.

> "*With varying doctors and trainees, you simply need to repeat things.(…) another group arrives from another hospital, with a different standard practice, where they were used to do things differently.*" (#9)

It was suggested, mostly by faculty, to assign dedicated staff to monitor outcome data and implement plans for improvement.

> "(*…) in task forces because they'll put it on their agenda and have something to say about that topic, about quality.*" (#11)

General lack of time was mentioned in all but one interview, as an important barrier to preparation, attendance and realisation of actions. Similarly, staff may face too many, sometimes conflicting, expectations.

> "*We expect single individuals to fulfil all these requirements for clinical practice, research, training, leadership ánd management (…) that's thé inhibiting factor! Too many tasks and too many different tasks.*" (#2)

Receiving dedicated time to work on tasks arising from M&M was perceived to facilitate these processes.

> "*We rather do it at night to avoid missing surgeries, clinic or clinical… that's the focus of our training, clinical practice.* (…) *If we decide, and acknowledge [that M&M is of equal importance], then I think that we should organise it in such a way that residents receive half a day to do these things.*" (#7)

Only two external-level factors were reported: the 'nature' of healthcare, balancing risks and benefits (e.g., haemorrhage and thrombosis prevention) was perceived to prevent complete eradication of adverse events, and benchmarking local performance against other centres was often mentioned as an important facilitator, serving as a source of information and motivator.

Pathways to M&M success

The reported facilitators and barriers appeared to enhance or impede whether professionals are:

1) adequately *informed* to identify targets and plans for improvement;
2) *motivated* to participate in, and support, M&M practice and the ensuing actions;
3) willing and able to *realise* plans of action and bring about change.

Hence, 'information', 'motivation', and 'realisation' seemed to serve as potential mediating pathways by which M&M drives learning and improvement (Table 2). These pathways could also affect each other as, for example, information can motivate by increasing sense of urgency, which may ultimately enhance realisation efforts.

DISCUSSION

This qualitative study identified 57 different barriers and facilitators to successful M&M practice perceived by healthcare professionals, together covering 17 themes. Many factors concerned organisational aspects, but others related to the individual or team level, such as personal motivation or group dynamics. All factors affected whether participants are (1) *motivated* to participate and take action; (2) well-*informed* to identify targets and plans for improvement; and (3) willing and able to *realise* plans; representing the mediating pathways to M&M-based learning and improvement.

An important strength of this study lies in the qualitative approach, yielding nuanced insights that quantitative assessments cannot reveal. To illustrate, qualitative analyses revealed the complexity of various factors, such as hierarchy or team spirit, which appeared to have both positive and negative effects at the same time. Moreover, data saturation was achieved and

Table 2. Mediating pathways to M&M-based learning and improvmeent that are affected by reported facilitators and barriers.

	**INFORMATION** *(to know)* i.e., complete/clear/accessible information, presentations, data/trends, communications, feedback, input/discussion, dissemination.
	**MOTIVATION** *(to want)* i.e., participant attendance, participation, experience, engagement, support, sense of urgency.
	**REALISATION** *(to can/do)* i.e., ensure a clear objective and extensive plan, feasibility, empowerment for change, follow-up/tracking, (re)evaluation, sustaining.

many factors and pathways described in the study appeared to closely relate to more general frameworks and theories of learning and change. An important limitation is the single centre design of this study. The findings may particularly be representative of teaching hospitals as interviewees worked at an academic hospital and their prior M&M experience was mostly at other teaching hospitals. However, qualitative research does not pursue generalizability, but rather aims to explore and develop a deeper understanding of a phenomenon of interest. As interviewees worked in surgery these findings may not be fully representative of all medical specialties that practise M&M. Additional qualitative research is required to reveal whether the same facilitators and barriers apply to other specialties. This is likely the case, as the generic mechanisms by which clinicians learn and improve through these conferences will be more similar. Research on M&M in other settings, such as paediatrics and psychiatry, highlight similar success factors, including resources (i.e., time and staff),[33,34] leadership buy-in and presence,[34,35] input from all staff levels,[33-36] and loop closure.[33,35] Furthermore, in a previous study, we found that departments with great variation in M&M practice shared the same expectations and challenges for M&M.[29] Moreover, the study findings appeared to fit well within the more general frameworks for learning and improvement in healthcare (Appendix 3).

Comparison with existing literature

While M&M practice has often been subject of study, this is, to our knowledge, the first qualitative study of M&M success factors. The present study adds novel insights into the roles of various individual- and social-level factors, perceived as barriers, facilitators or both simultaneously (Table 1) an example being 'team spirit', which was perceived as a potential facilitator

as well as barrier to openly voicing one's opinions or concerns at M&M. Thus far, individual or team-level factors have received scant attention in the M&M literature, with the exception of the importance of 'a blame-free culture'.[2,5,12,20,37] This study confirms the importance of a safe environment, but also provides leads about what the desired culture or 'mindset' for M&M encompasses. It seems that M&M should *elicit* input from all participants,[10,15,16] and truly *value* such input from all corners. In other words, attention needs to be given to both the *sender* and *receiver* end to harness a truly open mindset at the conference. The value of input from other disciplines was appreciated by interviewed professionals, but multidisciplinarity was also perceived as a potential threat to the open environment that is so important for M&M. This finding adds nuance to previous studies advocating for multidisciplinary M&M, expecting only positive effects.[10,37-39] This study revealed three mediating pathways by which M&M may successfully drive learning and improvement, which were related to information, motivation and realisation (Table 1). While the role of motivation has received little attention in prior M&M research, more general publications about organisational learning or improvement have stressed the important role of individual and team factors, such as motivation.[21–24] After all, leadership can create strategies and improvement plans, but this will be insufficient without commitment and support of front-line staff-"culture eats strategy for breakfast".[24,40,41] Pathways to M&M success described in this study appeared to closely relate to more general frameworks for improvement and implementation in healthcare (Appendix 3). We attempted to translate the findings of this qualitative study to actionable recommendations, enlisted in Table 3, targeting one or more of the described pathways to M&M success. Some of these recommendations have been reported in prior M&M studies, such as using local data[42,43] and extensive planning,[10] but others more closely relate to learning behaviour literature, such as sense of urgency, motivation and being receptive to new ideas.[21,23,24,41]

Implications for M&M practice

The recommendations formulated based on the study findings, address some aspects of M&M organisation, but also aim to target challenges at the level of the (individual) professionals (Table 3). Various complexities embedded in healthcare culture may complicate M&M practice, one of which is working with colleagues with different hierarchical or expertise levels. These professional boundaries might be overcome by promoting the desired mindset for M&M. As with the 'culture of shame and blame', which used to be infamous for its presence at M&M, these issues could be targeted with, for example, moderators and local leadership, guided by principles of Just Culture.[44,45] As mentioned in the interviews, seniors or leaders can model desired behaviour and attitudes at M&M, by openly discussing personal errors and addressing the emotional impact. This is confirmed by the, to our knowledge, only other qualitative study of M&M, conducted in internal medicine, which described this type of role-modelling at the conference.[46] For example, the conference could start with framing the purpose as collegial and non-blaming, as used in recently developed novel formats for M&M.[33-35]

Table 3. Recommendations for successful M&M practice based on identified facilitators and barriers, and mediating pathways for M&M-based learning and improvement.

Recommendation	*Further details (related themes in Table 1)*
1. URGENCY **Select topics relevant to the audience and demonstrate a sense of urgency.**	Ensure topics are applicable to one's own practice, clinically significant and accompanied by a sense of urgency, e.g., by supporting presentations with (local) data on incidences and harm (1,4,13).
2. INFORMATION **Maximize informativeness and attractiveness of presentations.**	Use well-prepared presenters, engagement of those involved in cases, and fixed presentation formats including case details, literature, local/benchmark data as well as system-level and soft/human factors (2,3,6).
3. PLANNING **Be explicit in terms of action items and follow-up.**	Determine who will do what, when, and how, with a plan for follow-up and re-evaluation (5,10,13).
4. MOTIVATION **Motivate participants through interactivity and feedback.**	Ensure that participants are motivated, e.g., by using moderators to promote interactivity and 'close the loop' on prior actions through evaluation and feedback (6,10-14).
5. ANTICIPATION **Consider feasibility of actions, and anticipate and counter problems.**	Anticipate and plan how to counter problems with realisation and sustaining of actions, e.g., due to complexity, lack of empowerment or engagement of all staff involved, or staff turnover (4,7,10).
6. INPUT **Draw upon collective expertise of participants.**	Ensure presence and input from all involved in care processes, e.g., by actively inviting comments from experts, juniors or other disciplines (7,9-11).
7. RECEPTIVITY **Cultivate an open mindset, receptive to all input and opportunities.**	Emphasize that input of all involved in care is essential and valued as such, and underline the need to be sensitive to 'weak signals' that may signal opportunities for improvement (7,9-13).
8. SETTING **Consider M&M meetings in specialist settings**.	In meetings on the subspecialty or multidisciplinary level ('integrated care'), participants may be more informed and in control as topics are more closely related to their daily practice (8,9,13,15).
9. RESOURCES **Dedicate time and staff to M&M practice and ensuing plans for improvement.**	Consider blocking time for attendance but also preparation and realisation of actions, and consider use of a dedicated committee or staff to implement plans that ensue from M&M (6,10,15).
10. DATA **Use local/benchmark data for information and (timely) feedback**	Ensure that data collection and monitoring systems are accessible to allow assessment of local performance, benchmarking against others and re-evaluation of prior plans for improvement (14,17).

There is no hierarchical order in this list. How recommendations relate to earlier published frameworks for improvement in healthcare and to mediating pathways, is depicted in Appendix 3.

An important question for future research appears to be how to motivate and engage all participants to receive the necessary input and support to actually improve clinical practice. Interviews reflected the paradoxical nature of hierarchy in this respect, as this can both help and hurt staff's motivation and support. Another solution may be to organise M&M in smaller, focused settings, such as subspecialties[15] or integrated care. Interviewees also perceived motivational effects of reviewing local or benchmark data and follow-up of actions from prior conferences, which could be incorporated into M&M practices to motivate participants and demonstrate the value of M&M.[5,20] More time for feedback and assessment of prior initiatives

would mean that fewer topics can be discussed at M&M or that extra time needs to be made available, but this would both be worthwhile considering the expected positive effects on achieving sustainable improvements.

CONCLUSIONS

This study enhanced understanding of the factors influencing M&M-based learning and improvement, and the pathways by which this occurs. Many factors were related to the individual or team rather than how M&M is organised. These insights may be used to improve M&M practices, and provide a framework for further study on determinants of M&M success. Future research is warranted to investigate success factors for M&M, and specifically the extent to which these are transferable to other settings, in order to design a universally applicable best practice for M&M.

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REFERENCES

1. Xiong X, Johnson T, Jayaraman D, et al. At the Crossroad with Morbidity and Mortality Conferences: Lessons Learned through a Narrative Systematic Review. *Can J Gastroenterol Hepatol* 2016;2016:1-11. doi:10.1155/2016/7679196.
2. Orlander JD, Barber TW, Fincke BG. The morbidity and mortality conference: the delicate nature of learning from error. *Acad Med* 2002;77:1001-6.
3. Aboumatar H, Blackledge C, Dickson C, et al. A Descriptive Study of Morbidity and Mortality Conferences and Their Conformity to Medical Incident Analysis Models: Results of the Morbidity and Mortality Conference Improvement Study, Phase 1. *Am J Med Qual* 2007;22:232-8.
4. Nasca T, Philibert I, Brigham T, et al The Next GME Accreditation System — Rationale and Benefits. *N Engl J Med* 2012;366:1051-6.
5. Sacks GD, Lawson EH, Tillou A, et al. Morbidity and Mortality Conference 2.0. *Ann Surg* 2015;262:228-9.
6. Macrae C. The problem with incident reporting. *BMJ Qual Saf* 2016;25:71-5. doi:10.1136/bmjqs-2015-004732
7. Cooke DL, Dunscombe PB, Lee RC. Using a survey of incident reporting and learning practices to improve organisational learning at a cancer care centre. *Qual Saf Heal Care* 2007;16:342-8.
8. Ginsburg LR, Chuang YT, Norton PG, Berta W, Tregunno D, Ng P, Richardson J. Development of a measure of patient safety event learning responses: Patient safety and public health. *Health Serv Res* 2009;44:2123-47.
9. Vincent C. Understanding and Responding to Adverse Events. *N Engl J Med* 2003;348:1051-6.
10. Bal G, Sellier E, Tchouda SD, et al. Improving quality of care and patient safety through morbidity and mortality conferences. *J Healthc Qual* 2014;36:29–36.
11. François P, Prate F, Vidal-Trecan G, et al. Characteristics of morbidity and mortality conferences associated with the implementation of patient safety improvement initiatives, an observational study. *BMC Health Serv Res* 2016;16:35. doi:10.1186/s12913-016-1279-8 [Published Online First: 30 January 2016].
12. Bechtold ML, Scott S, Dellsperger KC, et al. Educational quality improvement report: outcomes from a revised morbidity and mortality format that emphasised patient safety. *Postgrad Med J* 2008;84:211-6.
13. Gordon L. Gordon's Guide to the Surgical Morbidity and Mortality Conference. Philadelphia, PA, USA: Hanley and Belfus; 1994.
14. Murayama KM, Derossis AM, DaRosa DA, et al. A critical evaluation of the morbidity and mortality conference. *Am J Surg* 2002;183:246-50.
15. Gore DC. National survey of surgical morbidity and mortality conferences. *Am J Surg* 2006;191:708-14.
16. Risucci DA, Sullivan T, DiRusso S, et al Assessing educational validity of the Morbidity and Mortality conference: a pilot study. *Curr Surg* 2003;60:204-9.
17. Lecoanet A, Vidal-Trecan G, Prate F, et al. Assessment of the contribution of morbidity and mortality conferences to quality and safety improvement: a survey of participants' perceptions. *BMC Health Serv Res* 2016;16:176. doi:10.1186/s12913-016-1431-5
18. Harbison SP, Regehr G. Faculty and resident opinions regarding the role of morbidity and mortality conference. *Am J Surg* 1999;177:136-9.
19. Kim MJ, Fleming FJ, Peters JH, et al. Improvement in educational effectiveness of morbidity and mortality conferences with structured presentation and analysis of complications. *J Surg Educ* 2010;67:400-5.
20. Flynn-O'Brien KT, Mandell SP, Eaton E Van, et al. Surgery and Medicine Residents' Perspectives of Morbidity and Mortality Conference: An Interdisciplinary Approach to Improve ACGME Core Competency Compliance. *J Surg Educ* 2015;72:258-66.

21. Chuang Y-T, Ginsburg L, Berta WB. Learning from preventable adverse events in health care organisations: development of a multilevel model of learning and propositions. *Health Care Manage Rev* 2007;32:330-40.
22. Grol R, Wensing M. What drives change? Barriers to and incentives for achieving evidence-based practice. *Med J Aust* 2004;180:57-60.
23. Gibson C, Vermeulen F. A Healthy Divide: Subgroups as a Stimulus for Team Learning Behavior. *Adm Sci Q* 2003;48:202-39.
24. Carroll J, Edmondson A. Leading organisational learning in health care. *Qual Saf Heal Care* 2002;11:51-56.
25. Dicicco-Bloom B, Crabtree BF. The qualitative research interview. *Med Educ* 2006;40:314-21.
26. Francis JJ, Johnston M, Robertson C, et al. What is an adequate sample size? Operationalising data saturation for theory-based interview studies. *Psychol Health* 2010;25:1229-45.
27. O'Brien BC, Harris IB, Beckman TJ, et al. Standards for Reporting Qualitative Research. *Acad Med* 2014;89:1245-51.
28. Kievit J, Krukerink M, Marang-van de Mheen PJ. Surgical adverse outcome reporting as part of routine clinical care. *Qual Saf Health Care* 2010;19:e20. doi:10.1136/qshc.2008.027458
29. de Vos MS, Marang-van de Mheen PJ, Smith AD, et al. Towards Best Practices for Surgical Morbidity & Mortality Conferences: A Mixed Methods Study. *J Surg Educ.* doi:10.1016/j.jsurg.2017.07.002 [Published Online First:15 July 2017].
30. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77-101.
31. Saldaña J. *The Coding Manual for Qualitative Researchers*. London, UK: SAGE Publications Ltd; 2009.
32. de Vos MS, Smith AD, Shimizu N, et al. Surgical Quality Improvement Book (chapter 5): Morbidity and Mortality Conference: a Weekly Conference Designed to Improve Surgical Quality. http://www.brighamandwomens.org/Departments_and_Services/surgery/qiChapter5.aspx?sub=0 (Accessed 24 July 2017)
33. Cromeens B, Brilli R, Kurtovic K et al. Implementation of a pediatric surgical quality improvement (QI)-driven M&M conference. *J Pediatr Surg* 2016;51:137-42. doi:10.1016/j.jpedsurg.2015.10.032
34. Wasser T, Grunschel BD, Stevens A, et al. Transforming Systems of Care Through a Novel Resident-Led Approach to Morbidity and Mortality Conferences. *Acad Psychiatry* 2016;40:893-7. doi:10.1007/s40596-016-0606-z
35. Gerstein WH, Ledford J, Cooper J, et al. Interdisciplinary Quality Improvement Conference: Using a Revised Morbidity and Mortality Format to Focus on Systems-Based Patient Safety Issues in a VA Hospital: Design and Outcomes. *Am J Med Qual* 2016;31:162-8. doi:10.1177/1062860614555430
36. Frey B, Doell C, Klauwer D, et al. The Morbidity and Mortality Conference in Pediatric Intensive Care as a Means for Improving Patient Safety. *Pediatr Crit Care Med* 2016;17:67-72.
37. Kwok ESH, Calder LA, Barlow-Krelina E, et al. Implementation of a structured hospital-wide morbidity and mortality rounds model. *BMJ Qual Saf* 2017;26:439-48. doi:10.1136/bmjqs-2016-005459
38. Kauffmann RM, Landman MP, Shelton J, et al. The Use of a Multidisciplinary Morbidity and Mortality Conference to Incorporate ACGME General Competencies. *J Surg Educ* 2011;68:303-8.
39. Deis JN, Smith KM, Warren MD, et al. Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement. In: Advances in Patient Safety: New Directions and Alternative Approaches; Vol. 2: Culture and Redesign. http://www.ncbi.nlm.nih.gov/pubmed/21249895 (Accessed 23 March 2017).
40. Dixon-Woods M, Leslie M, Tarrant C, et al. Explaining Matching Michigan: an ethnographic study of a patient safety program. *Implement Sci* 2013;8:70.

41. Dixon-Woods M, McNicol S, Martin G. Ten challenges in improving quality in healthcare: lessons from the Health Foundation's programme evaluations and relevant literature. *BMJ Qual Saf* 2012;21:876-84. doi:10.1136/bmjqs-2011-000760
42. Hamby LS, Birkmeyer JD, Birkmeyer C, et al. Using Prospective Outcomes Data to Improve Morbidity and Mortality Conferences. *Curr Surg* 2000;57:384-88.
43. Hutter MM, Rowell KS, Devaney LA, et al. Identification of Surgical Complications and Deaths: An Assessment of the Traditional Surgical Morbidity and Mortality Conference Compared with the American College of Surgeons-National Surgical Quality Improvement Program. *J Am Coll Surg* 2006;203:618-24.
44. Martinez W, Lehmann LS, Hu Y-Y, et al. Processes for Identifying and Reviewing Adverse Events and Near Misses at an Academic Medical Center. *Jt Comm J Qual Patient Saf* 2017;43:5-15. doi:10.1016/j.jcjq.2016.11.001
45. Dekker S. *Just Culture: Restoring Trust and Accountability in Your Organisation.* Taylor & Francis Ltd; 2016.
46. Kuper A, Zur Nedden N, Etchells E, et al. Teaching and learning in morbidity and mortality rounds: an ethnographic study. *Med Educ* 2010;44:559-69.

APPENDIX

Appendix 1. Topic list for semi-structured interviews with attending surgeons and residents.

Introduction

- Background and objectives
- Information about interview (anonymity, safe)
- Information about participant: years of work experience at the department.

Morbidity and Mortality conference (M&M)

- How do you feel about M&M practice? What do you value? What do you miss/would you like to change?
- Do you consider M&M part of your profession (i.e., core business)?
- What affects whether learning occurs through M&M?
- What affects whether improvement occurs through M&M?
- What is the role of adverse event reporting in this?

Other topics:

Case selection

Prompts:

- What criteria should be used to select cases for M&M and why?
- Could a case of another surgical subspecialty be of educational value (to you)?

Presentation

Prompts:

- Who could best present the case and why? (senior or junior staff; involved in case or not)
- Would a fixed presentation format be beneficial or limiting?
- What information is essential to a successful M&M (e.g., local data)?

Attendance

Prompts:

- To what extent do logistic factors, e.g., OR schedules, influence M&M attendance rates?
- Would attendance rates benefit from mandatory attendance, e.g., with sign-in sheets, or from exemplary behaviour of staff?
- How would personal beliefs or motivation influence attendance rates?

Moderator

Prompts:

- Who could best moderate and how?
- To what extent does the moderator influence success of M&M (e.g., environment)?

Culture

Prompts:

- Is there an open environment, free of shame and blame? What illustrates or influences that?
- If you're at another department, how could you assess whether there is a blame-free culture?

- Example: a postoperative haemorrhage case is presented at M&M, you've also been present in the operating room and you now remember that you had doubts about haemostasis, would you mention that? What (potential) consequences could such a comment have?

Plans for improvement

Prompts:

- What affects whether formulated plans of action are successfully implemented?
- Are lessons explicitly formulated and documented? How would this affect implementation?
- How are plans tracked for implementation? Who should be responsible for this?

Appendix 2. Facilitators and barriers for successful M&M at different levels for achieving change in healthcare with quotes.

Theme	Facilitator (F) and/or barrier (B)	Illustrative quote
I) Case level		
Type of case	Attractive topic (F)	*'Surgery (…) something technical, you can visualize, (…) makes it easier to remember and to disseminate it to others(…) It might be more, well, fun, to learn about something 'operative'.'(#8)*
	Clinical relevance (F)	'*While some topics may be less interesting (…) pressure ulcers or hospital acquired pneumonia for example, these are still of clinical relevance.'(#1)*
	Value for education/ improvement(F)	*'A preference to discuss recent cases makes that you select a severe haemorrhage case while that actually went very well all year. It's key to identify and select real targets for improvement.'(#5)*
Information	Include local data (F)	*'Especially if you review your own numbers, that would provide valuable insights.'(#3)* *'(…) pneumonia, everyone will be like 'oh no, boring', but if you present a concise plan and numbers and those things, then, I think that'd be very nice, because that concerns everyone.'(#5)*
	Literature (F)	'*Why do I have to see 6000 graphs? (…) Just use the conclusions of the best papers (#1)'* '*Just a few relevant papers, somewhat related to your own patient population.'(#8)* '*Everyone thinks 'Well, how's our performance? Where are we compared to the literature?'(#9)* *'Nationally, globally, are we above or below the line?'(#11)*
	Skills education (F)	*'The presentation needs to include the very technical things, regarding surgical techniques.'(#6)* *'You just want to prevent those errors and that's purely technical I think.'(#10)*
	Information from those involved (F+B)	*F: 'If you've been involved, it's nice to present that case and the content benefits from it too.'(#9)* *B: 'The disadvantage of being emotionally involved is that you're sort of biased. [And can that bias impede learning?] Well yes, I think, cause it's only part of the story, from someone who's emotionally involved (…) difficult to keep it factual when the message is already 'coloured' .'(#7)*
	Addressing system factors (F)	'*I think, if the focus of the conference would shift towards system-level improvement, one would be more inclined to offer their opinion (…) it would yield more input.' (#5)*
	Addressing 'soft skills' (F)	'*That's where this conference should be about (…) because then you don't learn from each other about content knowledge, but behavioural aspects – something 'the department' still shares (#2)'* *'we are humans (…)let's go back to the moment it happened: What did you forget? What were you doing? Were you busy? (#7)*

Appendix 2. Facilitators and barriers for successful M&M at different levels for achieving change in healthcare with quotes. (continued)

Theme	Facilitator (F) and/or barrier (B)	Illustrative quote
Presentation	Qualified presenter (F)	'*It requires a skilful presenter otherwise, the pitfall is that it becomes a dry enumeration of things, while it should be lively, it's particularly all about the discussion.' (#11)*
	Proper preparation (F)	*[What makes that it does result in concrete targets?] 'The level of preparation by all means.' (#1)*
	Proper supervision (F)	*'As long as there's proper supervision. No, it's not about the presentation of course, it's about the well-thought construction of your story, all things sorted out and whether these are correct.'(#3)*
	Fixed format (F)	*'Yes I think that has benefits [a fixed format], it makes it easier to make, for residents, less time, and you don't provide them the space to stray off topic, that it'll get to lengthy.'(#4)*
II) Action level		
Type of plan	Attractive topic (F)	'*If it's about a thread that resorbs faster, we're all extremely eager to say: 'we should use thát!'(…) while if it's about antibiotics 1 day more or less, it really doesn't interest anyone.'(#1)*
	Clinically significant topic (F)	*'Patients might die (…) is life threatening, so then you've got an incentive to do something.'(#3)*
	More disciplines involved (B)	*'How many people in the organization are involved? Lessons [i.e., to improve future care] that involve thousands of stakeholders are more difficult than those you can realize on your own.' (#4)*
	Higher complexity (B)	*'Some things are technical, you can visualize them (…) a clear intervention, because you either do it or you don't – while others more greatly depend on multiple factors.' (#8)*
Planning	Explicitly formulated (F)	*'I think because, it is most interesting when you head home thinking 'Darn. I'll do that differently tomorrow'. (…) and preferably within 15 minutes. Short and concise'(#11)*
	Responsibility assigned (F+B)	*F: 'It shouldn't be non-committal, you should really earmark people.'(#11)* *B: 'If you just send someone off like 'you go do that', that won't work, it has been proven.' (#9)*
	Time frame determined (F)	*'Give it a month and then: 'Well a month ago we've discussed this, what has been done?' Then you really trigger someone.'(#5)* *'We'll discuss this in 3 months and then we'll assess progress, did anything change?' - that way it's not so vague. It will be remembered and will definitely have a follow-up attached to it. (#9)"*
	Included in protocols (F)	*'It's challenging to translate lessons learned into changes in protocols or policies, but once you've connected those, well yes, then you're really going to improve your quality. (#9)*

Appendix 2. Facilitators and barriers for successful M&M at different levels for achieving change in healthcare with quotes. (continued)

Theme	Facilitator (F) and/or barrier (B)	Illustrative quote
III) Individual level		
Motivation	Intrinsic motivation for QI (F)	*'In part it's about your motivation for that, that you just want to, just want to improve. If you're like 'it will all work out', yes, well, then nothing will happen.'(#1)*
	Interest in specific topic (F) (applicable, interest, urgency)	*'(…) when it's personal, when it's applicable to your own work, then you learn from it (…) also when it involves your own surgical service then it suddenly becomes top priority.'(#11)*
	Values/beliefs (F+B)	*F: '(…) experienced as a chore, which in itself isn't bad (…) some things are chores, but just need to be done' (#4)* *B:'If you consider your job to be solely about operating, then you're not interested (…)'(#11)*
	Other priorities/ incentives (B)	*'[residents] don't do it [free up time for actions], because we rather do it in the evening to avoid missing surgeries, clinic or clinical.. that's the focus of our training, clinical practice'(#7)*
Participation	Personality (F+B)	*F:'It has to do with the type you hire. If it's the timid, anxious – yes, well then little will be said. But if you hire people with a big mouth, you will hear a lot of talking but not a lot of content (…) I think, you should tell the juniors: listen, if you don't dare, then you shouldn't be here.'(#2)* *B: 'I think that [fear of speaking up] is in part related to personality, I want to avoid offending others, so that's something that has to do with me personally rather than the environment.'(#7)*
Realization	Empowerment, control (F)	*'If it's about knot X instead of Y, that's something we can execute, we understand that, we are in control for that, and thus we will do it. (…) Surgeons are particularly in control in the OR.' (#7)* *'No matter how hard I'd try if they [anaesthesia] won't do something then they don't want and I can't influence that; while if a certain thread has better outcomes, I can change that myself.'(#9)*
	Forgetfulness (B)	*'But we haven't done that [actions] yet. Just because other things receive priority and because you simply forget about it.' (#8)*
IV) Social level		
Culture	Safe environment (F)	*'There needs to be an open environment, non-judgmental, I think that is the crux of the matter, because otherwise you won't learn anything, people will put their foot down and get angry.' (#9)*
	Team spirit (F+B)	*F: 'They [subspecialty]know what I'm worth and I know their capacities, which creates a safe environment [for speaking up].' (#1)* *B: 'It's considered 'not done' - to not support each other [in discussions] – it's disloyal.' (#7)* *'Backstabbing undermines team spirit and most people in surgery are team players (…) so you'll always behave in the interest of the team.' (#8)*
	Super specialization (B)	*'It's not 'us surgeons' anymore, it's a totally different organization.'(#2)*

Appendix 2. Facilitators and barriers for successful M&M at different levels for achieving change in healthcare with quotes. (continued)

Theme	Facilitator (F) and/or barrier (B)	Illustrative quote
Leadership	Reinforcing attendance (F)	*'It sounds bland, but it works, someone who says angrily: 'You have to attend, I'm the boss.'(#4)*
	Reinforcing actions (F)	*'It works to promote action (…) that you'll fulfil your commitments (…) when you fear that if you won't do it you will get a roasting.'(#7)*
	Hierarchy (F+B)	*F: 'It's [attendance behaviour] more due to hierarchy, e.g., if attending X is always there, you'd need a good reason to be absent when X is there. He's got more important stuff to do than you, so it's probably important then. I definitely think that works.'(#3)* *B:'If you really want to promote free speech, then faculty should emphasize that hierarchy is put aside during such a meeting.'* (#7)
	Exemplary behaviour (F)	*'I think if you're a resident on a rotation and a faculty member will also be absent, they you'd think, well why would I go? Yes, it's a sort of exemplary role.' (#1)*
Participants	Participation of experts (F)	*'Input from someone with experience, more 'master level' in addition to trainees. (…) Yes, [someone involved in the case] with enough 'flight hours' to be able to evaluate it.' (#1)* *'It's about content experts. (…) Half of our faculty members don't even know how to prescribe medications with the hospital software, so they shouldn't say anything about that.'(#2)*
	Interactivity (F)	*'[moderators]can evoke discussion by asking stimulating questions giving people in the audience the opportunity to respond.' (#12)*
	Audience composition/ size (F+B)	*F: 'Some people are more receptive to critique than others.' (#4)* *'The conference benefits from high attendance rates.' (#8)* *B: 'Well that [courage to speak up] depends on who's present, their interests and whether you could damage people.(...) It's by all means safer to discuss things in a smaller group.' (#1)* *'I think in a smaller setting (…) less [plans] will 'get lost'. It's a disadvantage that you reach fewer people, but the advantage is that less is lost.' (#3)*
	Multidisciplinary participation (F+B)	*F: 'If a nurse was involved then she needs to be present too. (…) We could discuss interesting cases with other specialists (…) we can really learn a lot together.'(#6)* *B: 'For some, if, say, nurses and other people are present, you would perhaps be less inclined to tell your boss that something went not so well.'* (#5)
Moderation	Qualified moderator (F)	*'The role of the moderator, who has an important role in lowering the barrier [to speaking up] and be inviting, to create an environment that allows that. (#1)*

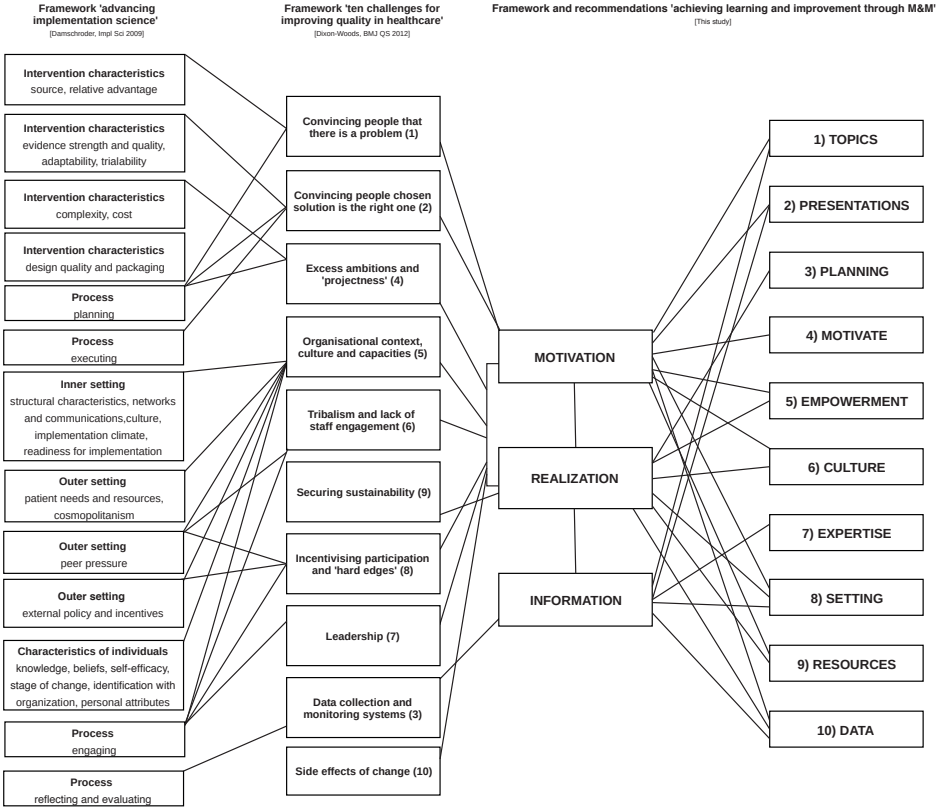
Appendix 2. Facilitators and barriers for successful M&M at different levels for achieving change in healthcare with quotes. (continued)

Theme	Facilitator (F) and/or barrier (B)	Illustrative quote
IV) Social level		
M&M format	Strong focus on improvement (F)	*'We should attribute more time to exploring how we're going to improve (…) this conference is meant to achieve improvement rather than to present the most exciting case of the month.'(#5)*
	M&M in specialist setting (F)	*'For subspecialist themes, I think the output will be much better if you'd discuss those in a smaller group within the surgical service, there will be a much safer environment too.'(#1)* *'Like love. I'm in love with my service and I'd do everything to ensure things run smoothly'(#6)* *'If it concerns your division, then you're really motivated to get those [complication] numbers down, then it suddenly becomes top priority.'(#11).*
	Communications (before/after) (F)	*'(…) to send out some sneak previews, that will motivate people to attend.' (#8)* *'If something derives from it, it'll be nice to know, but you'd have to keep the email short.'(#5)*
	Too many cases per meeting (B)	*'You won't make it [to discuss many cases] and it takes up so much energy and time, that you might miss lessons to be learned from cases.'(#8)*
	No tracking of actions (B)	*'And then what? It [action] ends up in a folder or email or something, that's not working.'(#3)* *'You'd have to check whether it was actually done. [Is it now?] No.' (#12)*
	No check/feedback on effect (B)	*'Did anything change? (…) Feedback needs to improve greatly, otherwise it's so useless.' (#10)* *'According to improvement cycles you need a check (...) also to see if it had the right effect.'(#12)*
Reporting	System for routine AE reporting (F)	*'You'd have to register otherwise you don't know what you're doing. It's a terrible task; I'm really bad at it. But yes, you have to, because you want to learn from your performance.'(#5)*
	Difficult access to data (B)	*'[Omitted because] it's a lot of work to retrieve data or we don't really know it that well.'(#12)*
	Lack of feedback from data (B)	*'The feedback is lacking. If you (…) only infrequently hear about an adverse event, you don't apply it to yourself. (…) It's all about feedback! Register, feedback, show the real world.'(#11)*

Appendix 2. Facilitators and barriers for successful M&M at different levels for achieving change in healthcare with quotes. (continued)

Theme	Facilitator (F) and/or barrier (B)	Illustrative quote
Staff	Dedicated quality committee/group (F)	'(…) *requires leadership to evoke actions at the right moments by saying 'OK now we have to do this and now that.' That requires a group within the department that stands for that.*' (#2). *'By embedding that [actions]in task forces because they'll put it on their agenda and have something to say about that topic, about quality.' (#11)*
	Super specialization (B)	*'It's difficult to find time to meet, because we all do different things. (…) We share the surgical department, but we don't share anything in terms of topics or daily practice.'(#2)*
	Staff turnover (B)	*'A hospital like this is run by temporarily staff, residents who rotate. You can't count on the collective memory, cause it disappears.' (#3)* *'Try to maintain such a thing! In the sense that, new people arrive constantly' (#4)*
	Other/conflicting expectations of staff (B)	'*As long as we expect single individuals to fulfil all these requirements for clinical practice, research, training, leadership ánd management - we'll miss important moments. (…) that is thé inhibiting factor! Too many tasks and too many different tasks.'(#2)* *'I find the work load on employees bizarre in certain cases. (…) It's just too much.'(#3)*
Time	Overall lack of time (B)	*'All conferences.. apparently everyone is a lot busier than 10 years ago. There's no time.'(#4)* *'To do a good job [as presenter], takes a lot of time. I think that's thé biggest bottleneck. I really think so, cause during working hours you just can't find the time for that.'(#12)*
	Receiving dedicated time for QI (F)	*'That [block OR time for M&M] provides you the space. (…) Apparently it's what we need.'(#9)* *'If we decide, and acknowledge [the importance], then give half a day.. I think that we should organize it in such a way, that residents receive half a day to do these things. We'd have to'.(#7)*
V) External level		
'Nature'	Inevitability of AEs (B)	*'Well.. whether you'd always learn from it.. in the sense that a year later they [AEs] will occur less often, I don't know. I think there's a certain lower limit you can't overcome.' (#4)*
Other hospitals	Benchmarking (F)	*'It's nice to benchmark to the rest of the world. How often does this happen here and somewhere else.. what are renowned centres, what're there numbers (…) can make it very urgent.'(#11)* *'If we exceed the global or European incidence rates, then you'd have a need to assess that trend.' (#6)*

Appendix 3. Relation of published frameworks for improvement in healthcare to this study's model of mediating pathways and practical recommendations.



From left to right: 'Consolidated Framework For Implementation Research' (CFIR)[1;] framework from 'Ten challenges for improving quality in healthcare'[2], and this study's pathways and recommendations for M&M.The relation between the first and second framework is depicted as described in the paper by Dixon-Woods et al.[2]

References:

1. Damschroder LJ, et al. *Implement Sci.* 2009;4:50.
2. Dixon-Woods M, et al. *BMJ Qual Saf* 2012;21:877-84.

Chapter 4

Learning from morbidity and mortality conferences: focus and sustainability of lessons for patient care

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ABSTRACT

Objectives

It remains unclear to what extent the morbidity and mortality conference (M&M) meets the objective of improving quality and safety of patient care. It has been suggested that M&M may be too focused on individual performance, hampering system-level improvement. Aim of this study was to assess focus and sustainability of lessons for patient care that derive from M&M.

Methods

Observational study of routinely collected data on evaluated complications and identified lessons at surgical M&M over 8 years, assessing type and recurrence of lessons and cases from which these were drawn. Semi-structured interviews with clinicians were qualitatively analyzed to explore factors contributing to lesson focus and recurrence.

Results

318 lessons were drawn from 10,883 evaluated complications, primarily for those that were more severe, related to surgical or other treatment, and occurring in non-emergent, lower risk cases (all P<.001). Most lessons targeted intraoperative (43%) rather than pre- or postoperative care, and specifically technical (87%) and individual-level issues (74%). There were 43 recurring lessons (14%), mostly about postoperative care (47%) and medication management (50%). Interviewed clinicians attributed the intraoperative, technical focus primarily to greater appeal and control, but identified an array of factors contributing to lesson recurrence, such as typical staff turnover in teaching hospitals.

Conclusions

This study provided empirical evidence that learning at M&M has a tendency to focus on intraoperative, technical performance, with challenges to sustain lessons for more system-level issues. M&M formats need to anticipate these tendencies to ensure a wide focus for learning with lasting and wide impact.

Key words: morbidity and mortality conference; patient safety; quality improvement; continuing education.

INTRODUCTION

The morbidity and mortality conference (M&M) is healthcare's oldest forum for learning and improvement. Following its introduction in the early 20th century this traditional 'golden hour of the surgical workweek'[1] has been adopted by many specialties outside of surgery.[2–4] While many studies have assessed M&M practice,[5] literature is scarce on the extent to which M&M actually meets the objective of improving the quality and safety of patient care.

An inherent problem in M&M research is that it is unrealistic to use changes in clinical outcomes (e.g. complication rates) to assess M&M success, as the conference's impact cannot be isolated from other advancements in clinical practice. Instead, the number of lessons learned at M&M may serve as a first measure of success.[4,6] However, M&M lessons are often not routinely documented and empirical studies of lessons are unavailable.[7,8] Despite this lack of evidence, there are indications M&M is too focused on individual performance rather than systems issues.[5,9–15] Such a narrow focus would be unsuccessful, as it has been widely acknowledged that addressing system-level factors is paramount to achieve sustainable improvements.[6,11,16]

This study assessed lessons learned at M&M of a surgical department with a robust and standardized process for reporting and evaluation of complications, including routine documentation of all lessons learned. Lessons were analyzed for frequency, type, related patient cases, and recurrence of similar lessons over time. In addition, surgical faculty and residents were interviewed to reflect on observations to gain more insight in factors contributing to the focus and recurrence of lessons. We hypothesized that the most frequent type of lessons would provide insight into the focus of learning at M&M, and that recurrence of lessons would reveal where it is more difficult to realize and sustain improvements.

METHODS

This observational study analyzed all routinely reported and evaluated complications, referred to as adverse events (AEs), of all surgical inpatients discharged from Leiden University Medical Center (LUMC) between January 2003 and April 2011. This time frame was selected because data collection, part of routine practice, was known to be very consistent and robust in that period, ensuring reliable data over various years. The LUMC is an 882-bed Dutch university hospital, in which the surgical department has an annual inpatient volume of approximately 3400 patients, covering general, endocrine, vascular, gastrointestinal, pediatric, oncologic, trauma and transplant surgery. In the Netherlands, an adverse event is defined as *any unintended or unwanted event or state occurring during or following medical care that requires adjustment of treatment or results in permanent damage.*[17] This definition excludes interpretation of causality from reporting, as it includes AEs related to underlying disease or comorbidities.

For institutions using the WHO definition that an AE is *an injury related to medical management, in contrast to complications of disease,*[18] this is referred to as a 'hospitalization-related AE' in the present study.

Reporting and evaluation process

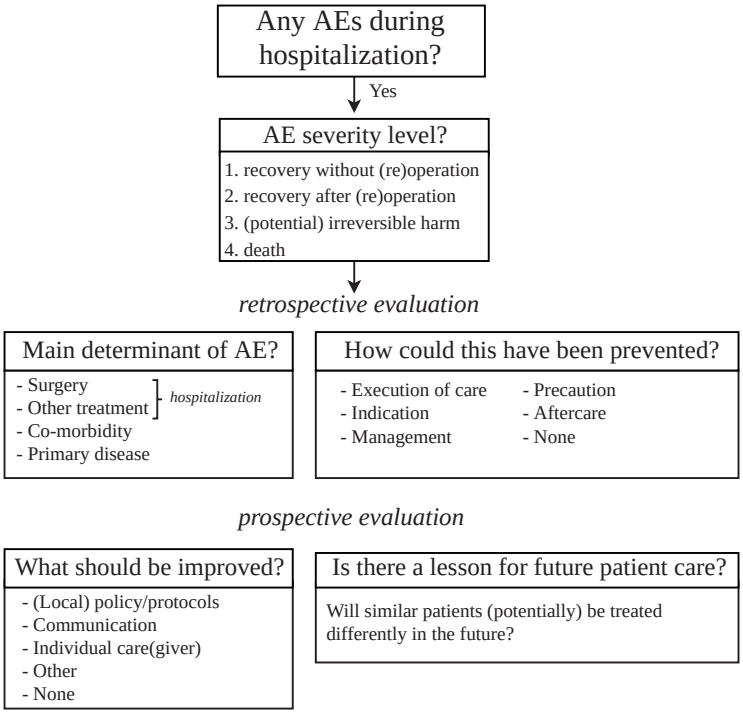
The process for routine AE reporting, implemented in 1997, has been described in prior publications, including its effectiveness being similar to record review.[17,19] Surgeons reported all AEs prospectively during admission or at patient discharge, and assigned severity levels reflecting consequences for the patient (Figure 1). AEs leading to reoperation, irreversible harm or death (i.e. severity level ≥2) or those with ≥3 AEs within an admission, were automatically selected for collective evaluation at M&M. Other AEs were individually evaluated by surgeons, who actively added an AE to M&M if they anticipated it would give rise to a lesson for patient care. The weekly M&M conference was mandatory for all surgical faculty, residents, physician assistants and medical students, and lasted about 1 hour. Cases were presented by residents responsible for the ward at time of patient discharge. The discussion was supported by literature reviewed by presenters and expert advice from the audience. All AE evaluations (collectively at M&M or individually by surgeons) followed a fixed format. First, the main determinant and preventability of the AE were determined in hindsight, then the forward-looking question was raised whether similar cases in the future should be treated differently to prevent this type of AE. If yes, this was documented as a 'lesson learned at M&M' along with any actions that arose (including categories for improvement, e.g. protocol change) (Figure 1).

Statistical analyses

For all AEs, admission data on patient age, gender, length of stay, American Society of Anesthesiologists (ASA) physical status and emergent or elective status at the first surgical procedure were included. Lessons were categorized based on which phase of care was targeted for improvement using categories used in a prior publication (Table 1).[21] Lessons regarding non-interventional care were categorized as postoperative. Discharge dates were used as dates of lessons. Recurring lessons were defined as *all lessons targeting a clinical issue similar to one or more preceding lesson(s)*, and were identified using manual text searches with sub-selections on phase of care and keywords for clinical topics.

AEs with and without lessons were compared using χ^2 tests and Fisher's exact test if expected count was less than five for categorical variables, and *t*-tests for continuous variables except length of stay (Mann-Whitney U test). All AEs had the potential to give rise to a lesson, either via automatic selection or manual submission to M&M, but there was no record of which cases had been manually added. Therefore, two estimates of AEs evaluated at M&M were obtained for analyses: an upper-bound estimate that included all reported AEs (main analysis), and a lower-bound estimate that included all AEs meeting criteria for automatic selection as well

Figure 1. Process of reporting and evaluation of adverse events.



Group evaluation at M&M of AEs in case of ≥3 AEs during admission, AEs severity ≥ 2 or if requested by reporting physicians. Other cases are evaluated by treating physicians during AE reporting according to the same format. 'Individual care(giver)' refers to improvements related to the care provided by the individual provider(s) in the specific case, such as improving individual technical skills or protocol adherence (e.g. 'amputation should have been performed sooner in this case').

as other AEs for which M&M lessons had been recorded (supplemental analysis). Statistical analyses were conducted using SPSS Statistics (IBM, v23) with a 0.05 alpha level.

To reflect on factors contributing to type and recurrence of lessons observed in this study, semi-structured interviews were conducted with 6 attending surgeons, 5 surgical residents in training, and 1 physician assistant (PA) (median local work experience: 5 years [1-18 years]). Participants were selected using purposive, heterogeneous sampling - varying gender, seniority and subspecialty - to obtain a diversity of viewpoints. Interviews were audio-taped, transcribed verbatim and analyzed with inductive, data-driven, thematic content analysis using qualitative analysis software (Atlas.ti, GmbH, v7).[22] Coding was performed by the interviewer (MdV), re-assessed by a research assistant and discussed until consensus was reached.

Table 1. Phases of care and subcategories used to categorize lessons that derived from M&M.

Phase of care	**Subcategories** *(example)*
Preoperative care	Indication *(time-to-surgery)*
	Workup *(imaging)*
	Medication *(antibiotic prophylaxis)*
	Communication *(planning the surgery)*
Intraoperative care	Technical aspects of surgery *(suturing)*
	OR circumstances *(instrument counting)*
	Operative medication *(blood transfusion in OR)*
Postoperative care	Postoperative management *(fluid management)*
	Medication *(heparin dosing)*
	Central venous catheters, urinary catheters and tubes *(nasogastric tube)*
	Physical care *(pressure ulcer prevention)*
	Communication *(medical record keeping)*

OR, operating room.

RESULTS

A total of 10,883 AEs were reported and evaluated in the study period, occurring in 5259 of all 28,539 (18.4%) inpatient admissions (Table 2). The most commonly selected main determinant for AEs was (surgical) treatment (i.e. hospitalization) (77.6% of 10,883), rather than primary disease (12.6%) or comorbidities (9.8%). A total of 318 AEs (2.9%) resulted in lessons learned, most of which were AEs considered preventable (98.7%) (Table 2). Among all 1626 AEs considered preventable (i.e. 15.0% of all AEs; 18.6% of hospitalization-related AEs), approximately 1 out of 5 resulted in a lesson (19.3% of 1626). Of the 4487 AEs related to surgery, 189 (4.2%) had lessons, and 4298 (95.8%) did not have lessons.

Cases from which lessons were drawn

AEs that gave rise to lessons had similar patient characteristics compared to AEs without lessons, except for lessons occurring more often in patients with lower ASA status and elective status (Table 2). Lessons were more often identified for more severe AEs, related to hospitalization, and specifically surgery (all P<.001).

At least 7106 AEs (65.3% of 10,883), occurring in 2336 inpatient cases, will have been collectively evaluated at M&M as they met selection criteria (i.e. ≥3 AEs or AE severity ≥2, n=7018) or had recorded lessons (n=88). In this subset, lessons were recorded for 4.5% of all AEs and 24.2% of all preventable AEs and differences regarding patient characteristics were similar, with the exception of significantly lower length of stay for AEs with lessons (Appendix 1).

Table 2. Differences between AEs that resulted in lessons and AEs without lessons.*

Variable	All AEs reported (N=10,883)		AEs with lessons n=318 (2.9)		AEs without lessons n=10,565		P
Age, years	60.3 ± 17.4		59.3 ± 18.7		60.3 ± 17.4		0.336
Male gender	6343	(58.3)	192	(60.4)	6151	(58.2)	0.422
Length of stay, days	29.7 ± 37.2		26.4 ± 35.8		29.8 ± 37.2		0.355
Underwent surgery	9753	(89.6)	292	(91.8)	9461	(89.6)	0.190
Status at first surgery†							
elective	6185	(63.4)	212	(72.6)	5973	(63.1)	0.004*
emergency	921	(9.4)	20	(6.8)	901	(9.5)	
missing	2647	(27.1)	60	(20.5)	2587	(27.3)	
ASA at first surgery†							
I	579	(5.9)	38	(13.0)	541	(5.7)	<0.001*
II	2773	(28.4)	96	(32.9)	2677	(28.3)	
III	2771	(28.4)	79	(27.1)	2692	(28.5)	
IV	732	(7.5)	11	(3.8)	721	(7.6)	
V	241	(2.5)	8	(2.7)	233	(2.5)	
missing	2657	(27.2)	60	(20.5)	2597	(27.4)	
Severity level							
1) recovery without operation	8284	(76.1)	162	(50.9)	8122	(76.9)	<0.001*
2) recovery with operation	1797	(16.5)	113	(35.5)	1684	(15.9)	
3) (potential) irreversible harm	316	(2.9)	29	(9.1)	287	(2.7)	
4) death	475	(4.4)	11	(3.5)	464	(4.4)	
undetermined	11	(0.1)	3	(0.9)	8	(0.1)	
Main determinant							
Surgery‡	4487	(41.2)	189	(59.4)	4298	(40.7)	<0.001*
Other than surgery	6389	(58.7)	129	(40.6)	6260	(59.3)	
Hospitalization‡	8439	(77.6)	295	(92.8)	8144	(77.1)	<0.001*
Other than hospitalization	2437	(22.4)	23	(7.2)	2414	(22.9)	
Preventability§							
Preventable	1626	(15.0)	314	(98.7)	1312	(12.5)	<0.001*
Not preventable	9207	(85.0)	4	(1.3)	9203	(87.5)	
By execution of care	1061	(9.8)	151	(47.5)	910	(8.7)	<0.001*
Not by execution	9772	(90.2)	167	(52.5)	9605	(91.3)	
Improvement‖							
Individual care(giver)	621	(5.7)	233	(73.7)	388	(3.7)	<0.001*
Non-individual	10,252	(94.3)	83	(26.3)	10,169	(96.3)	

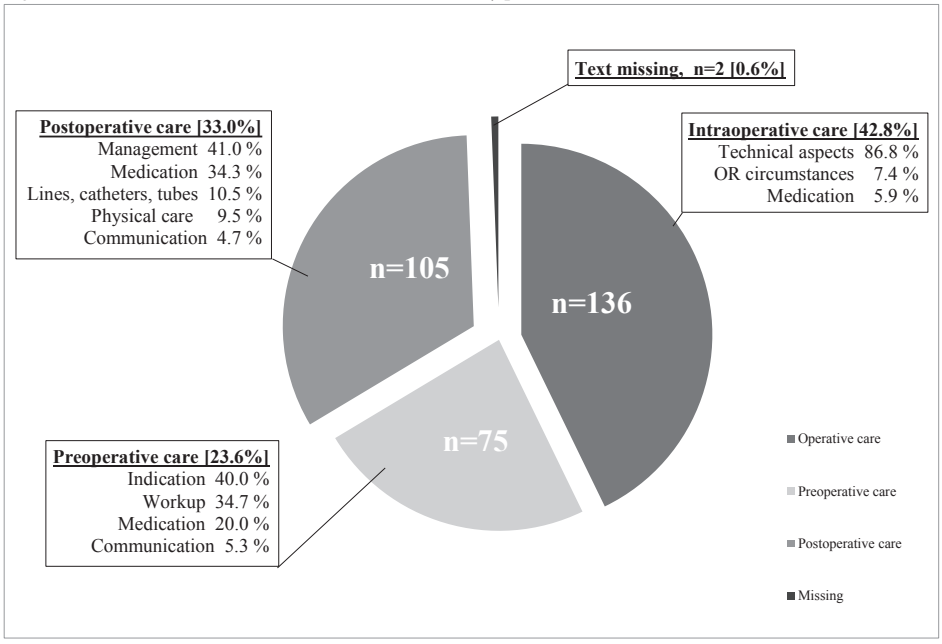
AEs, adverse events. *ASA*, American Society of Anesthesiologists physical status. Categorical data presented as number (column %, excl. missing), continuous data as mean ± standard deviation. * corresponds to P-value significant at the 0.05 level. † ASA and (non)-emergent status are recorded at first surgical procedure during admission, therefore these numbers are presented as % of all patients who underwent surgery (total reported AEs, n=9753; AEs with lessons, n=292; AEs without lessons n=9461). ‡ Surgery: main determinant surgery, rather than other treatment, comorbidity or primary disease. Hospitalization: main determinant surgery or other treatment, rather than comorbidity or primary disease. Missing for 7 AEs. § Missing for 50 AEs. || Missing for 10 AEs.

Type and recurrence of lessons

Most lessons concerned intraoperative care (n=136, 42.8%) and primarily technical aspects of surgery (86.8% of 136) rather than circumstances (7.4%) or medications (5.9%) in the operating room (Figure 2). Among lessons, 'individual care(giver)' (i.e. related to the specific case and provider(s), e.g. 'amputation should have been performed sooner in this case') was nearly three times more frequently selected (73.7%) than more system-level categories for improvement, such as 'communication' and 'protocols'. (Table 2). Among the 475 deceased patients, 11 AEs (2.3%) resulted in lessons, of which 8 (72.7%) were related to individual-level improvements.

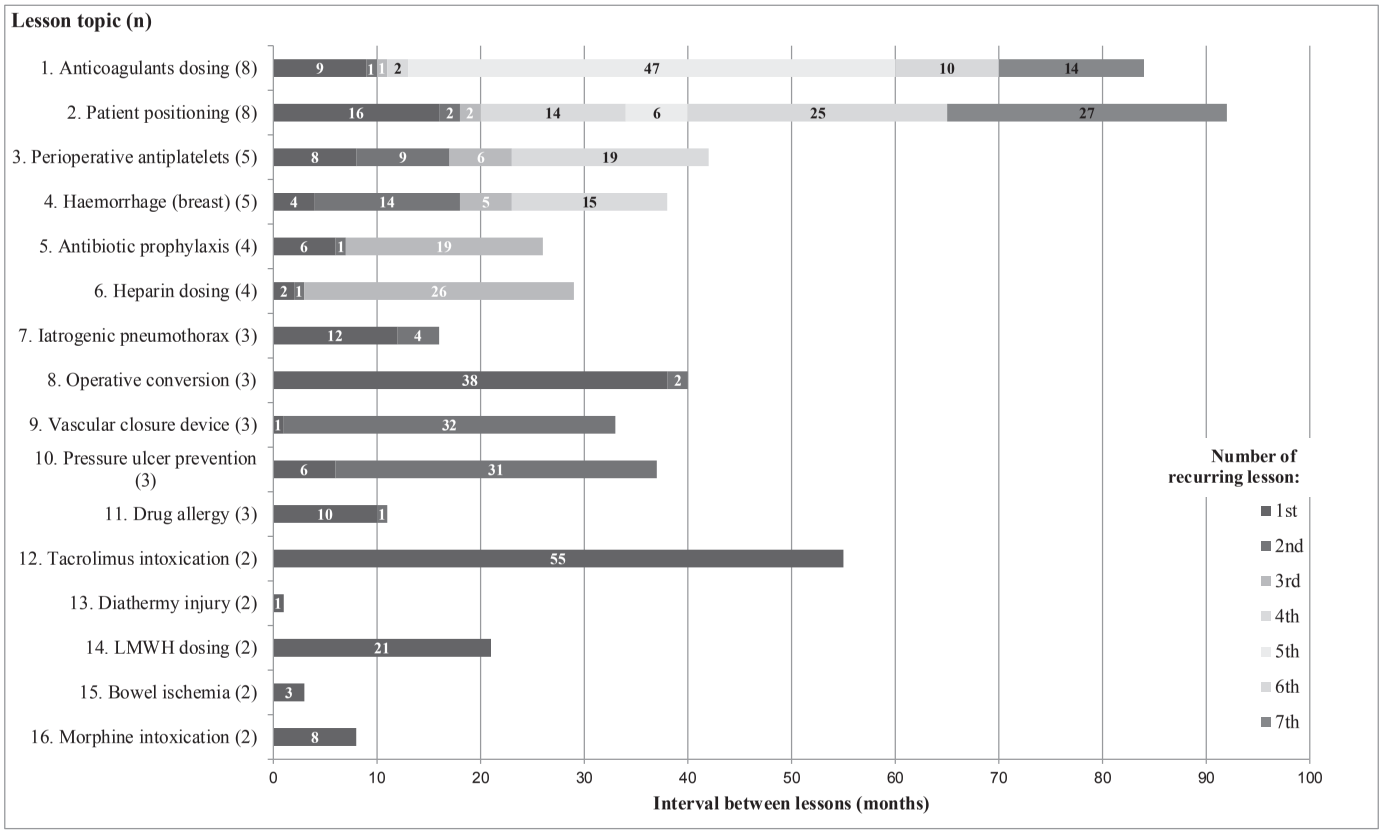
A total of 43 lessons (13.5% of 318) were recurring lessons following 16 similar lessons documented earlier in time (Figure 3). Most of these 43 recurring lessons concerned postoperative care (46.5%) (preoperative 9.3%; intraoperative 44.2%) (Appendix 2). Among recurring lesson topics, most concerned medication (50.0% of 16) (e.g. anticoagulants, morphine), followed by operative topics (37.5%) (e.g. patient positioning, intraoperative conversion from laparoscopic to open cholecystectomy) (Figure 3). Most recurring lessons were recorded in the first half of the study period (26 of 43 recurrences, 60.5%). To illustrate, recurring lessons on anticoagulants mostly derived from hemorrhagic AEs and called for improvements in International Normalized Ratio (INR) monitoring or associated protocols. On average, recurring lessons had a frequency of 2 per year with time intervals ranging widely (1-55 months).

Figure 2. All lessons that derived from M&M, stratified by phase of care (n=318).



OR, operating room.

Figure 3. Recurring lessons per topic with intervals (months) between subsequent lessons.



LMWH, low-molecular-weight heparin. Recurrence of similar lessons (initial lesson=0 on *x*-axis) with interval in months shown on each bar and total number of lessons at the end of bars (*n*). Intervals <1 month are displayed as '1'.

Most recurring lessons were identified for 'anticoagulant dosing' (8 in 7.3 years), 'patient positioning' (8 in 8.0 years) and 'perioperative antiplatelet therapy' (5 in 3.7 years) (Figure 3).

Contributing factors perceived by clinicians

Nearly all interviewed attendings and residents (11/12) attributed the predominance of intraoperative lessons to these being more appealing and more within a surgeon's control.

> *"I can do whatever but if they [anesthesiologists] don't order the next patient, then they just don't, so I cannot control that. While if another type of surgical thread will improve my results, then I'll change this myself." (#9)*

Recurrence of postoperative lessons was similarly attributed to lower appeal and less control for issues outside the operating room. However, 10 other factors were perceived to contribute to recurrence of lessons, such as sense of urgency and complexity. Appendix 3 presents all factors with illustrative quotes. Complexity of (sustaining) lessons was believed to increase with the number of people involved thus being harder for multidisciplinary care. Most frequently mentioned were 'typical staff turnover in teaching hospitals' and 'lack of protocol clarity/adjustments.'

> "*Well definitely the high turnover of staff [plays a role]. Not faculty but the team of residents changes every half year. People leave and new people arrive." (#12)*

'Staff turnover', 'multidisciplinary involvement' or 'control' were mostly mentioned by attendings (6 of 6 attendings vs. 3 of 6 residents/PA), while 'greater appeal' or 'protocol issues' were mostly reported by residents (2 of 6 attendings vs. 6 of 6 residents/PA) as factors contributing to lesson recurrence.

DISCUSSION

This study assessed lessons deriving from M&M over 8 years, and demonstrated what was learned, not learned and more difficult to learn through M&M. Lessons were recorded for 3% of all AEs and 19% of all AEs that clinicians deemed preventable. AEs that were more severe, related to (surgical) treatment, or occurring in non-emergent and lower risk cases, more commonly gave rise to lessons. While most lessons concerned intraoperative and technical performance, lessons that recurred over time mostly concerned postoperative care and medication management. Interviewed clinicians attributed this intraoperative, technical focus mainly to greater appeal and control for surgeons, but recurrence of lessons was attributed to an array of

factors, of which mostly mentioned were typical staff turnover in teaching hospitals and lack of protocol clarity or adjustments.

Individual focus

This study provided empirical evidence that lessons learned at M&M focused on individual and technical performance, even though the used format tried to also include system-level factors. These findings support prior indications that M&M may be too focused on the individual rather than the system level.[5,9–11,13-15] Individual responsibility is deeply embedded in surgical culture and improving technical skills is laudable and important.[23] However, achieving (sustainable) improvement frequently requires addressing more distant, system-related factors,[16,24,25] as also addressed in the ACGME core competency 'systems-based practice'.[26–29] A focus on individuals rather than the system, also increases the risk of blame, a widely acknowledged barrier to learning since landmark works such as Bosk's field study of surgical training,[23] Wachter's book on medical error,[30] and the Institute of Medicine's reports.[31,32]

While it has been shown that just as many determinants of complications can be identified in the pre- and postoperative as intraoperative phase of care,[7] most lessons learned at M&M appeared to target intraoperative issues in this study. Moreover, fewer lessons were drawn from higher risk cases and less severe AEs. This could be related to the fact that AEs may be considered more likely to occur in these higher risk cases, and hence more likely attributed to patient factors rather than considered a lesson for the future. This is in line with studies describing how feelings of ownership and control may affect reporting cases to M&M: cases with primarily 'medical' problems, incurable disease or less severe AEs tended not to be reported.[11,33] This study adds that these factors also affect the subsequent process of learning at M&M, even in a setting where many cases are automatically selected for the conference.

Preventability

Many AEs considered preventable did not result in lessons, which likely reflects how not all events considered preventable in hindsight also have implications for the care clinicians would provide to similar patients in the future. After all, preventability can be easily judged in the comfort of hindsight, but anticipating care for future patients (i.e. lessons) involves weighing all potential future risks and benefits while also considering clinical dilemmas and trade-offs involved. This quandary is reflected in the debate on AE preventability in the literature, where estimates range widely (18-62%).[34–37] This study adds to this debate, as it presents preventability rates judged by clinicians themselves (15% overall and 19% of hospitalization-related AE), which are lower than those of studies using external reviewers that lack context knowledge and strongly depend on accuracy and completeness of medical records.[35,38,39] This study's rate of 381 AEs per 1000 hospitalizations (i.e. 10,883 AEs in 28,539 patients) is close to that recently reported for surgical patients (368 per 1000).[40]

Recurring lessons

Recurring lessons can reveal areas with repetitive problems and stimulate increased attention to these matters. Overall, most lessons concerned intraoperative individual performance, but recurring lessons primarily addressed issues outside the operating room and/or involving multiple disciplines (e.g. medication management, patient positioning). Interviewed clinicians stressed that it can be particularly challenging to sustain improvements for activities mainly carried out by rotating residents with additional involvement of other disciplines. In theory, protocols can serve as a vehicle to propagate these lessons, but in actual practice, protocols may often be unclear or not updated, as also noted in interviews. The recurring lessons on perioperative antiplatelet therapy (i.e. aspirin cessation) and hemorrhage after breast surgery illustrate how particularly lessons that change local policies may trigger more recurring lessons. Protocols were changed but appeared to be incomplete or not adhered to in practice, which resulted in more lessons (Appendix 2).

That recurrence of lessons was less common in the later years of this study might indicate success of M&M. However, it may also be explained by the fact that these lessons had more time to have a recurrence than lessons in the last part of the study period. Moreover, there may be other reasons why lessons do not recur, for instance because the opportunity for learning is missed. Similarly, it is difficult to attribute changes in clinical outcomes to M&M success, as complications have various underlying causes and clinical practice is subjected to many other changes and improvements simultaneous to M&M. Instead 'recurring lessons' might be a better parameter to assess where M&M is less successful, revealing areas where prior lessons learned may not have been effective enough and require more attention.

Practical implications

A robust registry of lessons can be used to monitor the type of lessons learned at M&M and those recurring over time, as illustrated by this study. M&Ms with systematic documentation of plans for improvement have been shown to have greater effectiveness, in terms of number of (completed) improvement initiatives.[4] To ensure a realistic and systems approach to learning, M&M practices should be adapted to anticipate the observed tendency to focus on individual, intraoperative performance. Rather than reviewing single cases, discussing similar cases together, along with local and international data[41] on complications or other outcomes (e.g. incidents, complaints), may emphasize a system perspective and increase sense of urgency. Furthermore, this could occur at the subspecialty or ward level rather than department level**,** as staff may be more committed to 'their own' AEs (ownership) as well as more acquainted with, and more empowered to change (control), processes related to their own subspecialty. Issues relevant for all subspecialties can still be discussed at departmental conferences. Finally, greater multidisciplinary participation (i.e. medical specialists, nursing and paramedical staff) may widen the conference's focus beyond intraoperative care and increase the ability to achieve and sustain improvements, which requires early involvement of all who provide care.[42]

While multidisciplinary M&M would require substantial organizational efforts, this is recommended by recent M&M studies,[5,43,44] demonstrating positive effects on available information and teamwork.[9,26,27,45]

Strength and limitations

A strength of this study is that it reviewed a large number of complications routinely evaluated by surgeons along with the systematically collected lessons learned at M&M over 8 years. A limitation of this study is its inability to assess whether recorded lessons were adequate enough, completed or effective, hence it remains unclear whether non-recurring lessons were successful. While evaluations of complications are always affected by 'eye of the reviewer',[39] the fact that these largely took place in group discussions aided by fixed formats will likely have decreased inter-observer bias. Conceptions of quality and preventability may differ and alter over time, which needs to be taken into account when interpreting this study's estimates for preventability.[46] However, the generic mechanisms by which we learn from M&M are less likely to have changed in recent years. Therefore, we believe that the used data from 2003-2011, selected for consistency and reliability, are still timely and relevant. An important study limitation is that it remains unclear to what extent findings translate to other settings, particularly non-teaching hospitals. Nonetheless, while conducted at a single academic center, recurring lessons highlighted typical bottlenecks for surgical and inpatient care, reported to pose safety risks, such as medication management, specifically of anticoagulants.[35,40,47–50] Moreover, this study supports prior suggestions, made in other settings, that M&M may be too focused on individual and technical skills.[5,9–13] While M&M formats may differ between institutions, expectations and challenges for M&M practices are likely more similar,[51] which makes these findings relevant to others committed to learn through M&M and subsequently sustain lessons for patient care.

CONCLUSIONS

Lessons that derived from surgical M&M conferences over 8 years were mostly drawn from lower risk cases, more severe or surgery-related AEs, and primarily targeted individual intraoperative performance. Lessons recurring over time particularly concerned postoperative and medication management involving multiple disciplines. Future studies should test possible interventions to ensure a wide focus for learning at M&M and sustaining of lessons learned.

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REFERENCES

1. Gordon L. *Gordon's Guide to the Surgical Morbidity and Mortality Conference*. Philadelphia, PA: Hanley and Belfus; 1994.
2. Orlander JD, Barber TW, Fincke BG. The morbidity and mortality conference: the delicate nature of learning from error. *Acad Med*. 2002;77(10):1001-1006. doi:10.1097/00001888-200210000-00011.
3. Kwok ESH, Calder LA, Barlow-Krelina E, et al. Implementation of a structured hospital-wide morbidity and mortality rounds model. *BMJ Qual Saf*. June 2016:bmjqs-2016-005459. doi:10.1136/bmjqs-2016-005459.
4. François P, Prate F, Vidal-Trecan G, et al. Characteristics of morbidity and mortality conferences associated with the implementation of patient safety improvement initiatives, an observational study. *BMC Health Serv Res*. 2016. doi:10.1186/s12913-016-1279-8.
5. Xiong X, Johnson T, Jayaraman D, et al. At the Crossroad with Morbidity and Mortality Conferences: Lessons Learned through a Narrative Systematic Review. *Can J Gastroenterol Hepatol*. 2016. doi:10.1155/2016/7679196.
6. Tad-y D, Wald HL. The evolution of morbidity and mortality conferences. *BMJ Qual Saf*. 2016;(September):bmjqs-2016-005817. doi:10.1136/bmjqs-2016-005817.
7. Risucci DA, Sullivan T, DiRusso S, et al. Assessing educational validity of the Morbidity and Mortality conference: a pilot study. *Curr Surg*. 2003;60(2):204-209. doi:10.1016/S0149-7944(02)00735-3.
8. Antonacci AC, Lam S, Lavarias V, et al. A Morbidity and Mortality Conference-Based Classification System for Adverse Events: Surgical Outcome Analysis: Part I. *J Surg Res*. 2008;147(2):172-177. doi:10.1016/j.jss.2008.02.054.
9. Bal G, Sellier E, Tchouda SD, et al. Improving quality of care and patient safety through morbidity and mortality conferences. *J Healthc Qual*. 2014;36(1):29-36.
10. Bechtold ML, Scott S, Dellsperger KC, et al. Educational quality improvement report: outcomes from a revised morbidity and mortality format that emphasised patient safety. *Postgrad Med J*. 2008;84(990):211-216. doi:10.1136/qshc.2006.021139.
11. Hutter MM, Rowell KS, Devaney LA, et al. Identification of Surgical Complications and Deaths: An Assessment of the Traditional Surgical Morbidity and Mortality Conference Compared with the American College of Surgeons-National Surgical Quality Improvement Program. *J Am Coll Surg*. 2006;203(5):618-624. doi:10.1016/j.jamcollsurg.2006.07.010.
12. Pierluissi E, Fischer M, Campbell A, et al. Discussion of medical errors in morbidity and mortality conferences. *JAMA*. 2003;290(21):2838-2842. doi:10.1001/jama.290.21.2838.
13. Antonacci AC, Lam S, Lavarias V, et al. A Report Card System Using Error Profile Analysis and Concurrent Morbidity and Mortality Review: Surgical Outcome Analysis, Part II. *J Surg Res*. 2009;153(1):95-104. doi:10.1016/j.jss.2008.02.051.
14. Dimick JB, Greenberg CC. Understanding Gaps in Surgical Quality: Learning to Count What Cannot Be Counted. *Ann Surg* 2013;257:6-7. doi:10.1097/sla.0b013e31827ba13d
15. Mosher BD, Anderson CI, Nelson C, et al. The significance of nontechnical root causes in morbidity and mortality conference: The delivery of surgical care as a science. *J Am Coll Surg*. 2014;209(3):S96.doi:10.1016/j.jamcollsurg.2009.06.240.
16. Vincent CA, Moorthy K, Sarker SP, et al. Systems Approaches to Surgical Quality: From Concept to Measurement. *Ann Surg* 2004;239: 475-482. doi:10.1097/01.sla.0000118753.22830.41
17. Kievit J, Krukerink M, Marang-van de Mheen PJ. Surgical adverse outcome reporting as part of routine clinical care. *Qual Saf Health Care*. 2010;19(6):e20. doi:10.1136/qshc.2008.027458.

18. World Alliance for Patient Safety. WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. Geneva: World Health Organization; 2005.
19. Marang-van de Mheen PJ, van Hanegem N, Kievit J. Effectiveness of routine reporting to identify minor and serious adverse outcomes in surgical patients. *Qual Saf Health Care*. 2005;14(5):378-382. doi:10.1136/qshc.2004.013250.
20. Marang-van de Mheen PJ, Stadlander MC, Kievit J. Adverse outcomes in surgical patients: implementation of a nationwide reporting system. *Qual Saf Health Care*. 2006;15(5):320-324. doi:10.1136/qshc.2005.016220.
21. Marang-van de Mheen PJ, van Bockel J, Baas-Thijssen M, et al. Van complicatieregistratie naar kwaliteitsverbetering (Dutch). In: *Patient Safety in the Netherlands*. Assen, the Netherlands: Koninklijke Van Gorcum BV; 2005:127-140.
22. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3(2):77-101. doi:10.1191/1478088706qp063oa.
23. Bosk CL. Forgive and Remember: Managing Medical Failure. Chicago, IL: Chicago University Press; 1979.
24. Lipira LE, Gallagher TH. Disclosure of adverse events and errors in surgical care: Challenges and strategies for improvement. *World J Surg*. 2014;38(7):1614-1621. doi:10.1007/s00268-014-2564-5.
25. Sutcliffe KM. Defining and classifying medical error: lessons for learning. *Qual Saf Heal Care*. 2004;13(1):8-9. doi:10.1136/qshc.2003.008987.
26. Aboumatar H, Blackledge C, Dickson C, et al. A Descriptive Study of Morbidity and Mortality Conferences and Their Conformity to Medical Incident Analysis Models: Results of the Morbidity and Mortality Conference Improvement Study, Phase 1. *Am J Med Qual*. 2007;22(4):232-238.
27. Kauffmann RM, Landman MP, Shelton J, et al. The Use of a Multidisciplinary Morbidity and Mortality Conference to Incorporate ACGME General Competencies. *J Surg Educ*. 2011;68(4):303-308. doi:10.1016/j.jsurg.2011.02.002.
28. Flynn-O'Brien KT, Mandell SP, Van Eaton E, et al. Surgery and Medicine Residents' Perspectives of Morbidity and Mortality Conference: An Interdisciplinary Approach to Improve ACGME Core Competency Compliance. *J Surg Educ*. 2015;72:e258-e266. doi:10.1016/j.jsurg.2015.05.015.
29. Sacks GD, Lawson EH, Tillou A, et al Morbidity and Mortality Conference 2.0. *Ann Surg*. 2015;262(2):228-229. doi:10.1097/SLA.0000000000001268.
30. Wachter R, Shojania K. *Internal Bleeding*. New York, NY: Rugged Land; 2004.
31. Institute of Medicine. To Err Is Human: Building a Safer Health System. Washington, DC: National Academy Press; 1999.
32. Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press; 2001.
33. Feldman L, Barkun J, Barkun A, et al. Measuring postoperative complications in general surgery patients using an out- comes-based strategy: Comparison with complications presented at morbidity and mortality rounds. *Surgery*. 1997;122(4):711-720.
34. Marang-van de Mheen PJ, Hollander EJF, Kievit J. Effects of study methodology on adverse outcome occurrence and mortality. *Int J Qual Heal Care*. 2007;19(6):399-406. doi:10.1093/intqhc/mzm039.
35. de Vries EN, Ramrattan MA, Smorenburg SM, et al. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care*. 2008;17(3):216-223. doi:10.1136/qshc.2007.023622.
36. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ*. 2001;322(7285):517-519. doi:10.1136/bmj.322.7285.517.

37. Zegers M, de Bruijne MC, Wagner C, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Heal Care*. 2009;18(4):297-302. doi:10.1136/qshc.2007.025924.
38. Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer. *Jama*. 2001;286(4):415-420. doi:10.1001/jama.286.4.415.
39. Hogan H. The problem with preventable deaths. *BMJ Qual Saf*. 2016;25(5):320-323. doi:10.1136/bmjqs-2015-004983.
40. Wang Y, Eldridge N, Metersky ML, et al. National Trends In Patient Safety for Four Common Conditions, 2005-2011. *N Engl J Med.* 2014; 370(4): 341-351. doi:10.1056/NEJMsa1300991.
41. Hamby LS, Birkmeyer JD, Birkmeyer C, et al. Using Prospective Outcomes Data to Improve Morbidity and Mortality Conferences. *Curr Surg*. 2000;57(4):384-388.
42. Pronovost PJ, Goeschel CA, Colantuoni E, et al. Sustaining reductions in catheter related bloodstream infections in Michigan intensive care units: observational study. *BMJ*. 2010;340:c309. doi:10.1136/bmj.c309.
43. Calder LA, Kwok ESH, Adam Cwinn A, et al. Enhancing the quality of morbidity and mortality rounds: The Ottawa M&M model. *Acad Emerg Med*. 2014;21(3):314-321. doi:10.1111/acem.12330.
44. Kirschenbaum L, Kurtz S, Astiz M. Improved clinical outcomes combining house staff self-assessment with an audit-based quality improvement program. *J Gen Intern Med*. 2010;25(10):1078-1082. doi:10.1007/s11606-010-1427-5.
45. Deis JN, Smith KM, Warren MD, et al. Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement. In: *Adv Patient Saf New Dir Altern Approaches (Vol 2 Cult Redesign)*. Agency for Healthcare Research and Quality (US) 2008. http://www.ncbi.nlm.nih.gov/pubmed/21249895. Accessed 15 Jan 2017.
46. Vincent C, Amalberti R. Safety in healthcare is a moving target. *BMJ Qual Saf*. 2015;24(9):539-540. doi:10.1136/bmjqs-2015-004403.
47. Symons NRA, Almoudaris AM, Nagpal K, et al. An Observational Study of the Frequency, Severity, and Etiology of Failures in Postoperative Care After Major Elective General Surgery. *Ann Surg* 2013;257:1-5. doi: 10.1097/sla.0b013e31826d859b
48. Hoonhout LHF, de Bruijne MC, Wagner C, et al. Nature, Occurrence and Consequences of Medication-Related Adverse Events During Hospitalization. *Drug Saf*. 2010;33(10):853-864. doi:10.2165/11536800-000000000-00000.
49. Howard RL, Avery AJ, Slavenburg S, et al. Which drugs cause preventable admissions to hospital? A systematic review. *Br J Clin Pharmacol*. 2007;63(2):136-147. doi:10.1111/j.1365-2125.2006.02698.x.
50. Damen NL, Baines R, Wagner C, et al. Medication-related adverse events during hospitalization: a retrospective record review study in the Netherlands. Pharmacoepidemiol Drug Saf 2017; 26: 32–39. doi:10.1002/pds.4037
51. de Vos MS, Marang-van de Mheen PJ, Smith AD, et al. Toward Best Practices for Surgical Morbidity and Mortality Conferences: A Mixed Methods Study. *J Surg Educ*. Published Online First: 15 July 2017. doi:10.1016/j.jsurg.2017.07.002

Appendix 1. Sub analysis: differences between AEs with and without resulting lessons among a subset of AEs that have been evaluated at M&M (i.e. all AEs meeting automatic selection criteria and other AEs with recorded lessons).

Variable[1]	*AEs evaluated at M&M* n=7106[2]		*AEs with lessons* n=318 (4.5)		*AEs without lessons* n=6788		*P*
Age, years	60.7± 17.0		59.3 ± 18.7		60.7 ± 16.9		0.193_
Male gender	4279	(60.2)	192	(60.4)	4087	(60.2)	0.952_
Length of stay, days	39.0 ± 42.2		26.4 ± 35.8		39.7 ± 42.3		<0.001*
Underwent surgery	6552	(92.2)	292	(91.8)	6260	(92.2)	0.796_
Status at first surgery[3]							
elective	4001	(61.1)	212	(72.6)	3789	(60.5)	<0.001*
emergency	622	(9.5)	20	(6.8)	602	(9.6)	
missing	1929	(29.4)	60	(20.5)	1869	(29.9)	
ASA classification[3]							
I	261	(4.0)	38	(13.0)	223	(3.6)	<0.001*
II	1581	(24.1)	96	(32.9)	1485	(23.7)	
III	1916	(29.2)	79	(27.1)	1837	(29.3)	
IV	644	(9.8)	11	(3.8)	633	(10.1)	
V	215	(3.3)	8	(2.7)	207	(3.3)	
missing	1935	(29.5)	60	(20.5)	1875	(30.0)	
Severity level							
1) recovery without operation	4507	(63.4)	162	(50.9)	4345	(64.0)	<0.001*
2) recovery with operation	1797	(25.3)	113	(35.5)	1684	(24.8)	
3) (potential) irreversible harm	316	(4.4)	29	(9.1)	287	(4.2)	
4) death	475	(6.7)	11	(3.5)	464	(6.8)	
undetermined	11	(0.2)	3	(0.9)	8	(0.1)	
Main determinant[4]							
Surgery	2960	(41.7)	189	(59.4)	2771	(40.9)	<0.001*
Other than surgery	4139	(58.3)	129	(40.6)	4010	(59.1)	
Hospitalization	5268	(74.2)	295	(92.8)	4973	(73.3)	<0.001*
Other than hospitalization	1831	(28.8)	23	(7.2)	1808	(26.7)	
Preventable	1299	(18.4)	314	(98.7)	985	(14.6)	<0.001*
Not preventable	5763	(81.6)	4	(1.3)	5759	(85.4)	
By execution of care	6218	(88.0)	151	(47.5)	693	(10.3)	<0.001*
Not by execution	844	(12.0)	167	(52.5)	6051	(89.7)	
Improvement[6]							
Individual care(giver)	539	(7.6)	233	(73.7)	306	(4.5)	<0.001*
Non-individual	6557	(92.4)	83	(26.3)	6474	(95.5)	

Categorical data presented as number (column %, excl. missing) and continuous data as mean ± standard error. * corresponds to P-value significant at the 0.05 level. [2] These 7106 AEs were reported for a total of 2336 inpatient admissions. [3] These variables represent ASA and (non)-emergent status recorded at first surgical procedure during admission, therefore these numbers are presented as % of patients who underwent surgery (AEs evaluated at M&M, n=6552; AEs with lessons, n=292; AEs without lessons, n=6260). [4] Surgery: main determinant surgery, rather than other treatment, comorbidity or primary disease. Hospitalization: main determinant surgery or other treatment, rather than comorbidity or primary disease. Missing for 7 AEs. [5] Missing for 44 AEs. [6] Missing for 10 AEs.

Appendix 2. Recurring lessons with dates and related adverse events.

Shared topic of recurring lessons (n)	Date	Lesson content (phase: preoperative (I), intraoperative (II) or postoperative (III))[1]	Related adverse event
1. Anticoagulants dosing (8)	06/2003	Lack of protocol for perioperative management of patients with ulcers, antacids and anticoagulants. (I)	Hemorrhagic shock
	04/2004	Do not just continue dosing. Protocols need adjustment to meet patient subgroups' needs (elderly). (III)	INR elevation
	06/2004	INR monitoring was too short. (III)	Hemorrhage with INR elevation
	08/2004	INR lab results from weekend were not communicated, was measured without order but elevated! (III)	Hemorrhage with INR elevation
	11/2007	Anticoagulants dosing according to the newest protocol as explained by internal physician. (III)	Arterial bypass re-occlusion
	08/2008	Better monitoring of INR after cessation of anticoagulant therapy. (III)	Subcutaneous hemorrhage
	07/2009	Inquire which dose patients normally take at home. (III)	INR elevation
	09/2010	In case of treatment with split skin graft (SSG), stop anticoagulant therapy. (III)	Hemorrhage foot
2. Patient positioning (8)	03/2003	Improve positioning on operating table (prone position and leg rests). (II)	Occluded vascular prosthesis leg
	07/2004	Improve patient positioning for long surgeries.(II)	Peroneal neuropathy
	10/2004	Proper patient positioning. (II)	Peroneal neuropathy
	01/2005	Improve positioning on operating table or Intensive Care Unit (ICU) bed. (II)	Peroneal neuropathy
	03/2006	Pay attention to position of extremities in every intervention or ICU stay. (II)	Ulnar neuropathy
	10/2006	Properly place arm on arm rest. (II)	Ulnar neuropathy
	11/2008	Too much peroneal neuropathy in compartment syndrome case. (II)	Peroneal neuropathy
	03/2011	Beware of too much abduction or too high elevation of arms in anesthetized patients.(II)	Brachial plexus paresis
3. Perioperative antiplatelet policy (5)	02/2003	Antiplatelet therapy should be discontinued at an earlier stage prior to surgery. (I)	Postponed surgery
	11/2003	I(nter)national literature supports continuation of antiplatelet therapy because of stroke risk. (I)	Stroke
	08/2004	More precise, thorough hemostasis should be obtained in surgeries under antiplatelet therapy. (II)	Intraoperative hemorrhage
	03/2005	Suboptimal management: anesthesia has wrongfully discontinued antiplatelet therapy. (I)	Stroke
	11/2006	Again, antiplatelet therapy was wrongfully discontinued. This needs further exploration. (I)	Postoperative hemorrhage breast
4. Hemorrhage (breast surgery) (5)	04/2005	Department's policy/protocol has changed: postoperative drainage. (III)	Postoperative hemorrhage breast
	08/2005	Non-adherence to protocol. Refer to our hospital's protocol database. (III)	Postoperative hemorrhage breast after heparin administration
	11/2006	Again, antiplatelet therapy was wrongfully discontinued. This needs further exploration. (I)	Postoperative hemorrhage breast
	04/2007	Many hemorrhage problems in tissue expanders, sub pectoral preparation otherwise. (II)	Postoperative hemorrhage breast
	07/2008	Increase focus on hemostasis after surgery. (II)	Postoperative hemorrhage breast
5. Antibiotic therapy (4)	03/2005	What are the criteria for antibiotics in case of suspected wound infection? (III)	Wound infection leg/hip
	09/2005	Are there more undiagnosed wound infections due to a more aggressive antibiotic policy (e.g., more wound infections in cases with osteosynthesis material but less osteomyelitis?) (III)	Wound infection leg/hip
	09/2005	More aggressive antibiotic policy, 'preventative therapy'? (III)	Wound infection foot
	05/2007	Reconsider antibiotic prophylaxis, convert to prolonged antibiotic therapy (e.g., five days). (III)	Recurrent sub hepatic abscess

Appendix 2. Recurring lessons with dates and related adverse events. (continued)

Shared topic of recurring lessons (n)	Date	Lesson content (phase: preoperative (I), intraoperative (II) or postoperative (III))[1]	Related adverse event
6. Heparin dosing (4)	03/2003	Inadequate dosing of heparin. (III)	Postoperative hemorrhage
	05/2003	Inadequate dosing of heparin. (II)	Infected hematoma transplant
	06/2003	Improve heparin dosing. (III)	Catheter-induced hemorrhage
	08/2005	Non-adherence to protocol. Refer to our hospital's protocol database. (III)	Postoperative hemorrhage breast after heparin administration
7. Iatrogenic pneumothorax (3)	10/2004	Reassess protocols on pneumothorax after central line placement (drainage or not) (III)	Catheter-induced pneumothorax
	11/2005	Ultrasound-guided central line placement. (II)	Catheter-induced pneumothorax
	03/2006	Line placement in recovery room was not ultrasound-guided. (II)	Catheter-induced pneumothorax
8. Operative conversion (3)	12/2003	When in doubt about anatomy, always convert to open surgery, especially in case of infiltrate. (II)	Bile duct injury (laparoscopy)
	03/2007	In laborious procedures, timely conversion to open surgery. (II)	Bile duct injury (laparoscopy)
	06/2007	Convert sooner or call for assistance. (II)	Bile duct injury (laparoscopy)
9. Vascular closure device use (3)	09/2005	Be aware of complications of angioseal. (II)	Arterial occlusion angioseal
	10/2005	A lot of patency loss due to angioseal 5/150. Ultrasound check of patency? Local calcifications? (II)	Arterial occlusion angioseal
	06/2008	Do not use angioseal in superficial femoral artery. (II)	Arterial occlusion angioseal
10. Pressure ulcer prevention (3)	01/2004	Pressure ulcer prevention. (III)	Pressure ulcer heels
	07/2004	Pressure ulcer prevention? (III)	Pressure ulcer heels
	03/2007	Pressure ulcer prevention was insufficient. (III)	Pressure ulcer heels
11. Drug allergy (3)	09/2004	Received nitrofurantoin despite known allergy. (III)	Allergic reaction to antibiotics
	07/2005	How do we deal with allergies? (III)	Allergic reaction contrast agent
	08/2005	Read health records thoroughly. (III)	Allergic reaction contrast agent
12. Tacrolimus intoxication (2)	03/2004	Intravenously. (III)	Tacrolimus intoxication
	10/2008	Tacrolimus administration orally instead of intravenously. (III)	Tacrolimus-induced nerve injury
13. Diathermy injury (2)	01/2003	Do not put away the diathermy instrument on the patient's skin. (II)	Contact burn (diathermy)
	02/2003	Diathermy was placed on the patient's unprotected skin. (II)	Contact burn (diathermy)
14. LMWH dosing (2)	07/2008	Given body weight and pregnancy, a double dose of fraxiparin was indicated. (III)	Deep venous thrombosis (leg)
	05/2010	Double dose of fraxiparin is indicated for all pelvic fractures. Moreover, patient > 90 kilograms. (III)	Pulmonary embolism
15. Bowel ischemia (2)	01/2010	When anastomosis is in venous trajectory, first use heparin (IV) as thrombosis prophylaxis. (II)	Small bowel thrombosis
	05/2010	This lesson has been formulated recently! (II)	Small bowel ischemia
16. Morphine intoxication (2)	04/2004	In case of pin-point pupils: no analgesia, no full dose opiates (IM, subQ). (III)	Morphine intoxication
	01/2005	What is the relation between age and morphine intoxication? (III)	Morphine intoxication

[1] Lessons translated from Dutch to English. This table depicts 43 recurring lessons and the 16 initial lessons that preceded these. Phases of care among the 43 recurring lessons: preoperative (n=4, 9.3%), intraoperative (n=19, 44.2%), postoperative (incl. non-interventional care) (n=20, 46.5%).

Chapter 5

Connecting perspectives on quality and safety: patient-level linkage of complaint, incident and adverse event data

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ABSTRACT

Background and objective

Incident, adverse event (AE) and complaint data are typically used separately, but may be related at the patient level with one event triggering a cascade of events, ultimately resulting in a complaint. This study examined relations between incidents, AEs and complaints that co-occurred in admissions.

Methods

Independently and routinely collected incident, AE and complaint data were retrospectively linked for surgical admissions in an academic centre (2008-2014). Two investigators reviewed whether incidents/AEs in admissions were clinically related and in what sequence (incident preceding vs following AE). Likelihood of occurrence of AEs and AE cascades (ie, ≥3 AEs) was studied using logistic regression analyses.

Results

Complaints were filed for 33 (0.1%) of 26,383 admissions. Complaints filed by patients with incidents and/or AEs (n=13) mostly addressed quality/safety problems, whereas other complaints mostly addressed relationships problems. Incidents and AEs co-occurred in 730 (2.8%) admissions, which seemed clinically related in 34% of these cases. Incidents with related AEs preceded as well as followed AEs (56.6%/44.4%). Patients with incidents were at greater risk of AEs than patients without incidents, even for seemingly unrelated AEs (OR 1.4; 95% CI 1.3 to 1.6). Risk of AE cascades was greater when patients with AEs also had incidents, regardless of whether these seemed related (unrelated: OR 2.0; 95% CI 1.6 to 2.5; related: OR 5.7; 95% CI 4.3 to 7.4) or whether incidents preceded or followed AEs in these admissions (53% vs 52%, p>.05).

Conclusions

Patient-level linkage of incident, AE and complaint data can reveal relations between events that otherwise remain obscured, such as that incidents trigger as well as follow AEs, introducing event cascades, regardless of whether clinical relations seem present.

Key words: quality improvement, quality measurement, patient safety, incident reporting, adverse events, epidemiology and detection.

INTRODUCTION

Most hospitals have installed systems to collect quality and safety data, such as incidents, adverse events (AEs) and patient complaints. Previous studies have demonstrated that these systems each identify different types of issues.[1-5] This would support using various approaches independently, and then synthesizing the messages from each approach to inform improvement programs.[1] However, although each system captures different signals from the same patient journey, these may be related at the patient level. Some of these relations are obvious, but others can be less clear, such as when an AE makes a patient more vulnerable and increases case complexity, triggering a chain of events. Insight into (perhaps still unknown) relations between co-occurring events may be obtained by linking these data at the patient level. In contrast to previous studies that examined different systems for their accuracy to detect the same events,[2,3,5,6] this study focuses on the relations between different events collected for the same admissions by independent systems.

The primary purpose of quality and safety data is to offer a 'window' onto the system, revealing underlying risks that need further investigation.[7–9] However, in isolation, these data may not be used to their full potential. To illustrate, record review looks back to assess whether patient harm can be linked to preceding substandard care – if so, this is considered an AE. Incident reporting assesses the same relationship in the opposite direction by reporting suboptimal care processes and whether these cause harm. Thereby, these approaches identify one-on-one relations in one direction, ie, from process to subsequent harm. Real clinical practice is more complex, and events within a single admission can have many-to-many relations, which could also be in the opposite direction when initial harm triggers subsequent process problems (eg, delirium → incident with dislodged intravenous line → haemorrhage → anaemia → transfusion incident). Current methods are only able to capture patient harm with known relations with (problems in) care processes. After all, if the relation between a process problem and patient harm is yet unknown, the harm would not be considered an 'AE' by record reviewers because they are unaware of the relation with medical management, and these problems would not be considered 'harmful incidents' by reporters.

Linkage of the various information sources on incidents, AEs, and complaints could potentially offer a more comprehensive view,[10] allowing a more sophisticated analysis of (relations between) events occurring in the same admission. This would also connect different perspectives, as incidents are typically reported by nurses,[4,11] whereas AE data are collected by physicians or from their notes in records, and complaints are filed by patients and their families. The Dutch healthcare system has three independent reporting systems to collect data on incidents, AEs and complaints, which each have a slightly different purpose and content (Table 1). Aim of this study was to examine relations between incidents, AEs and complaints, separately reported for the same admissions, including how one event may trigger a cascade

of events. This was done by retrospectively linking independent data systems for all patients hospitalised at an academic surgical department in a period of seven years.

Table 1. Features of the independent data collection systems for incidents, adverse events and complaints used in this study.

	Incident reporting	Adverse event (AE) reporting	Patient complaints handling
Targeted information	Process problems (regardless of patient harm)	Patient harm (regardless of process problems)	Patients' negative experiences with healthcare or hospital services
Local implementation	Implemented in 2008, and required for all Dutch hospitals since 2016	Implemented in 1997,[17] and a governmental quality indicator since 2004*	Has long been in place, but a complaints officer is required since 2016
Reporters	All medical staff but mostly nurses	Physicians, residents or physician assistants	Patients and their families
Nature of reports	Short stories that describe how a process problem happened (e.g. medication error)	Medical term (e.g. surgical site infection) and severity score reflecting consequences for patients	Short or longer letters explaining why patients are unsatisfied (e.g. felt not taken seriously)
Data storage	Reports are reported into, and stored in, a hospital-wide digital database (on paper until mid-2011), and reviewed by a dedicated committee	Reporting system is integrated in electronic medical records (on paper until mid-2011), and data are stored in a digital format.	Archived in binders rather than in digital databases by complaints handling office[22] with copies sent to departments involved
Strengths and limitations	Unique in revealing hazards before harm is inflicted, but unfit for monitoring due to risk of underreporting and unknown number of patients at risk (denominator)	Useful for benchmarking and to inform patients on AE risks, but risk of underreporting and lacks of contextual information (eg, whether preventative measures were taken)	Unique information from the patient perspective to reveal issues not captured elsewhere, but unstructured data of low and unreliable volume[22]

* In 2004, at least 75% of the Dutch hospitals had adverse event registries for interventional specialties, such as surgery, gynecology and orthopedics.

Methods

This retrospective cohort study linked all routinely and independently collected incident, AE and complaint data, for all 26,383 surgical inpatients discharged from a Dutch academic hospital between January 2008 and December 2014. As complaints may be lodged up to two years after hospitalisation,[12] those received between January 2008 and June 2016 were included. The requirement for ethical approval was waived by the local Ethics Committee (#P15.352) based on the Dutch Medical Research Involving Human Subjects Act.

Definitions

An incident is defined as *an event or circumstance which could have resulted, or did result in unnecessary harm to a patient,* which follows the WHO definition.[13] Incidents are process problems that can be harmful (ie, causing AEs) or non-harmful (ie, reportable circumstances, near misses or no-harm incidents).[13] As in many other countries,[3,9,14] Dutch hospitals ac-

tively encourage reporting of harmful as well as non-harmful incidents.[15] It is common in the patient safety literature to refer to harmful incidents as merely 'adverse events',[14,16] but this study distinguishes incidents (process problems regardless of patient harm) from AEs (harm regardless of process problems).

AEs represent undesired outcomes for patients, not all of which are necessarily preventable and caused by (observable) incidents. In the Netherlands, an AE is defined as *any unintended or undesired event or state, occurring during or following medical care, that is so harmful to a patient's health that adjustment of treatment is required or that permanent damage results.*[17] This definition overlaps with the commonly used WHO definition (ie, *injury caused by medical management rather than underlying disease*[13]), but also covers AEs related to underlying disease because the definition does not require judgement on the cause of the AE at time of reporting.

Patient complaints are defined as *letters of complaint sent to the hospital by patients or on behalf of patients.*

Reporting systems

Incidents and AEs are separately collected by independent reporting systems (Table 1). These systems are not intended to capture the same events, but rather to offer insights into process problems regardless of outcomes (incident reporting) versus adverse patient outcomes regardless of the quality of processes (AE reporting). Incident reporting is similar to that in many other hospitals, with incidents reported by all clinical staff, but mostly by nurses, in a hospital-wide electronic system.[3,14] Incident reports are short stories and usually also allow to report whether the specific incident was harmful or not. Therefore, this widespread method is only able to capture patient harm that has a one-on-one, well-known relation with the reported incident.

AEs are reported by physicians in electronic medical records during patients' stay.[17–19] AE reports only include medical terms (eg, septic shock) and severity scores reflecting consequences for patients, ie, 1) recovery without (re)operation; 2) recovery after (re)operation; 3) (potential) irreversible harm; 4) death.[18] AEs with severity ≥2 are considered 'serious AEs'. For the present study, 'AE cascades' are defined as ≥3 AEs within the same admission.

Many other settings use record review to detect AEs rather than physician reporting. A prior study estimated that this type of physician-driven reporting underestimates annual AE rate by only 1.8% compared to retrospective record review.[18] A benefit of this type of AE reporting combined with the Dutch definition, is that all undesired outcomes are recorded without the need to identify causes in medical management,[17–19] simplifying reporting and capturing a broad range of events. Because record review only captures AEs that can be related to (preceding) medical management, it will likely miss AEs related to process problems in ways that are yet unknown, or through a combination of events rather than a one-on-one relation.

Patient complaints are collected by the complaints handling and patient service offices, with copies sent to the departments involved (Table 1).

Data linkage and methods

AEs were already linked to corresponding admissions, but incidents could only be linked using patient identifiers and reporting dates (available for 2708 of 3001 incidents [90.2%]). Incidents were matched if identifiers were equal and if the reporting date of the incident was on or between admission and discharge date, resulting in 2162 (79.8% of 2708) incidents matched to 1599 admissions. Most unmatched incidents had misspelled patient identifiers or concerned non-surgical patients (62.0%), and in other cases reporting dates seemed to be misspelled. Of the 104 complaints received by the surgical department (January 2008-June 2016), 43 were for inpatient admissions in the study period, of which 33 could be linked to admissions using patient identifiers and dates in letters.

Complaints were categorized using the Healthcare Complaints Analysis Tool (HCAT), scoring problems on clinical (ie, quality and safety of care), management and relational domains (ie, behaviour of staff towards patients and their family/friends).[20] Incidents and AEs were classified using the WHO framework[16] and a previously developed AE classification scheme.[17]

To assess whether incidents and AEs in the same admission were clinically related, an MD-researcher (MdV) scored the likelihood of a clinical relation (ie, unlikely, potentially or likely) for all potential incident/AE pairs in admissions. For related incidents/AEs, the most likely sequence (incident *preceding* or *following* AE) was also scored. All potentially or likely related incident/AE pairs were additionally reviewed and scored by a second investigator (practicing research nurse [JC]) and discussed until consensus was reached.

To assess whether data linkage of independent reporting systems could reveal well-known relations between incidents and AEs, two clinical themes were selected a-priori: 1) delirium and patient accident incidents (using the WHO incident type, eg, falls or line removal); and 2) venous thromboembolism (VTE; ie, deep vein thrombosis or pulmonary embolism) and incidents with VTE prophylaxis (ie, low-molecular-weight heparin). Theme 1 represented an incident expected to frequently co-occur with the AE and to *follow* the AE, whereas theme 2 represented an incident expected to less frequently co-occur with the AE but to *precede* the AE.

Two AE types, wound infections and anastomotic leakage, were selected a-priori to study whether incident co-occurrence would increase risk of AE cascades. For patients with wound infections, incident co-occurrence was expected to increase risk of AE cascades as it may further increase patient vulnerability, while anastomotic leakage was considered a more severe AE and hence expected to be associated with AE cascades regardless of incident co-occurrence.

Statistical analyses

Statistical analyses were conducted using SPSS Statistics (IBM, v23) with a 0.05 alpha level. Complainants were compared to non-complainants on patient characteristics (age, gender, undergoing surgery or not, American Society of Anaesthesiologists (ASA) physical status and emergency status at the first surgery, length of stay and presence of readmission within 30 days), overall and separately for cases with both incidents and AEs. χ^2 tests were used for

categorical variables (Fisher exact test if expected count was less than 5), with Kruskal-Wallis H tests for age and length of stay and Mann-Whitney U test for number of incidents/AEs. Complaints for admissions with versus without incidents and/or AEs were compared on HCAT domains to study whether these addressed different issues.

To study co-occurrence, admissions with only incidents, only AEs, both incidents and AEs, and neither incidents nor AEs, were compared on the patient characteristics mentioned above. Complaints were assessed separately because of their low volume. The groups were compared on complaints filed, number of incidents/AEs, AE severity, and occurrence of serious AEs and AE cascades. Multivariable logistic regression was then performed to assess whether incident occurrence increased risk of AEs after adjustment for patient characteristics (age, gender, undergoing surgery or not and ASA status), both for all AEs and for seemingly unrelated AEs. Similarly, we assessed whether risk of long length of stay (ie, upper quintile) or readmission was increased for cases with both incidents and AEs rather than cases with only AEs.

To study risk of AE cascades, multivariable logistic regression was used among cases with AEs, comparing cases with (unrelated or related) incidents to cases without co-occurring incidents, adjusted for patient characteristics as above. The same analyses were performed conditional on having wound infections or anastomotic leakage. Consequences of AE cascades were assessed by studying risk of long length of stay and readmission for cases with AE cascades rather than only 1-2 AEs, using multivariable logistic regression adjusted as above.

RESULTS

Patient complaints

Complaints were filed for 33 of the 26,383 admissions (0.1% or 1.3 per 1000) (Figure 1). Most complaints were filed for cases without incidents/AEs (n=20, 60.6%) (Table 2). Complainants were similar to non-complainants in all patient characteristics (data not shown), except for a longer length of stay (median: 6 vs 3 days; p=.015). Admissions with complaints seemed more likely than those without complaints to have both incidents and AEs, but group sizes varied greatly (4/33 [12.1%] vs 726/26,350 [2.8%]; p=.001) (Figure 1). Complaints for admissions with incidents and/or AEs mostly addressed problems on the clinical domain (85% of 13), whereas other complaints mostly addressed the relational domain (75% of 20). In addition, in incident reports filed for 10 admissions, staff expressed complaints on behalf of patients or family (eg, "felt not taken seriously" or "not informed about transfer to intensive care unit"), but none of these were filed as formal complaints.

Figure 1. Occurrence of complaints, incidents and adverse events in admissions.

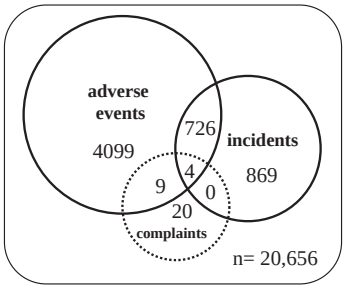


Table 2. Characteristics of admissions with or without adverse events and/or incidents.[1]

Variable n (column %)	***Cohort*** 26,383 (100.0)	***Neither AEs/I*** 20,676 (78.4)	***Only I*** 869 (3.3)	***Only AEs*** 4108 (15.6)	***Both AEs/I*** 730 (2.8)	***P***
Complaint filed	33 (0.1)	20 (0.1)	0 (0)	9 (0.2)	4 (0.5)	.006
No. of incidents						
total	2162	-	1024	-	1138	
median	0.0		1.0		1.0	<.001
mean	0.1±0.4		1.2 ±0.5		1.6 ±1.1	
No. of AEs						
total	8870	-	-	6897	1973	<.001
median	0.0			1.0	2.0	
mean	0.3±1.0			1.7 ±1.6	2.7 ±2.5	
Maximum AE severity*						
no AEs	21,545 (81.7)					
1	3353 (12.7)			2901 (70.6)	452 (61.9)	
2	829 (3.1)	-	-	665 (16.2)	164 (22.5)	<.001
3	225 (1.0)			192 (4.7)	63 (8.6)	
4	322 (1.2)			287 (7.0)	35 (4.8)	
undetermined	79 (0.3)			63 (1.5)	16 (2.2)	
Serious AEs (severity ≥2)	1406 (5.3)			1144 (27.8)	262 (35.9)	<.001
AE cascades (≥3 AEs)	845 (3.2)	-	-	581 (14.1)	264 (36.2)	<.001
Male gender	14,009 (53.1)	10,765 (52.1)	490 (56.4)	2298 (55.9)	456 (62.5)	<.001
Age (years)	52.6 ±21.0	50.7 ±21.4	58.5 ±16.2	59.6 ±18.3	61.1 ±15.3	<.001
Received surgery	19,154 (72.6)	14,288 (69.1)	664 (76.4)	3525 (85.8)	677 (92.7)	<.001
ASA at first surgery†						
I	4620 (24.1)	4198 (29.4)	72 (10.8)	335 (9.5)	15 (2.2)	
II	6619 (34.6)	4968 (34.8)	240 (36.1)	1242 (35.2)	169 (25.0)	
III	2428 (12.7)	1346 (9.4)	136 (20.5)	772 (21.9)	174 (25.7)	<.001
IV	225 (1.2)	79 (0.6)	7 (1.1)	121 (3.4)	18 (2.7)	
V	31 (0.2)	8 (0.1)	1 (0.2)	18 (0.5)	4 (0.6)	
missing	5231 (27.3)	3689 (25.8)	208 (31.3)	1037 (19.4)	297 (43.9)	
Status at first surgery†						
elective	11,284 (58.9)	8837 (61.8)	383 (57.7)	1804 (51.2)	260 (38.4)	<.001
emergency	2639 (13.8)	1762 (12.3)	73 (11.0)	684 (19.4)	120 (17.7)	
missing	5231 (27.3)	3689 (25.8)	208 (31.3)	1037 (29.4)	297 (43.9)	
Length of stay (days) mean	6.83 ±12.0	4.50 ±7.5	7.76 ±7.9	14.49 ±17.6	28.7 ±29.1	<.001
median	3.0	2.0	6.0	10.0	19.0	
Followed by readmission‡	2666 (10.1)	1643 (7.9)	97 (11.2)	791 (19.3)	135 (18.5)	<.001

AE, adverse event. *I*, patient safety incident. *No,* number. *ASA*, American Society of Anesthesiologists.

* Severity levels: 1) recovery without (re)operation; 2) recovery with (re)operation; 3) (potential) irreversible harm; 4) death.

† ASA and emergent (rather than elective) status at the first surgical procedure during admission, thus only available for cases who received surgery and presented as % of patients who received surgery (ie, total n=19,154).

‡ Whether a readmission followed within 30 days after discharge.

Co-occurrence of incidents and adverse events

Incidents were reported for 1599 (6.1%) admissions, mostly by nursing staff (71.2%). Annual incident rates doubled following implementation of electronic reporting in 2011 from 3-4% to 8%. AEs were reported for 4838 (18.3%) admissions, with annual AE rates ranging from 16.8% (2010) to 19.5% (2014). For 730 (2.8%) admissions, both incidents and AEs were reported (Figure 1). More than half of all incidents (52.6% of 2162) were reported for patients with AEs, whereas 22.2% of all AEs (n=8870) were reported for cases with incidents. Most common incident type was medication (4.0% of all admissions) and most common AE type was infection (7.3%), which were also the most common types to cluster in admissions (data not shown).

Patient characteristics differed between groups with and without incidents/AEs (Table 2). Looking at the data, patients with incidents and/or AEs seemed older, more often undergoing surgery and less often ASA 1-2 compared with other patients (Table 2). In multivariable analysis, adjusted for patient characteristics, incident occurrence and AE occurrence were significantly associated (OR 3.0; 95% CI 2.7 to 3.3). Compared with patients with only AEs, patients with both AEs/incidents had more incidents and AEs, and more often serious AEs (Table 2), and increased risk of long length of stay (OR 3.8; 95% CI 3.1 to 4.8) but not of readmission (OR 1.0; 95% CI 0.8 to 1.2).

Clinical relations

In 248 of the 730 (34.0%) admissions with co-occurring incidents and AEs, one or more clinical relations between incidents and AEs were identified (n=322 pairs). These included 36 unreported AEs mentioned in incident reports. In total, there were 4590 admissions with standalone or seemingly unrelated AEs, including 482 admissions with only unrelated incidents/AE and 4108 admissions with only AEs. Multivariable analysis showed that incident occurrence also increased the risk of these standalone/seemingly unrelated AEs (OR 1.4; 95% CI 1.3 to 1.6), after adjustment for patient characteristics.

AE types that were commonly related to co-occurring incidents included 'psychological disturbance' (eg, delirium), 'symptoms without diagnosis' (eg, metabolic abnormality) and 'rejection/allergy', whereas 'shock' or 'fistula' were only rarely related (Table 3). Incidents of the 'patient accident' type (eg, falls, unplanned removal of lines) were more often related than unrelated to co-occurring AEs (68.7%), whereas, for example, only 11-13% of the incidents about documentation and administration had clinically related AEs (Table 3).

Sequence

Among the 322 pairs of related incidents/AEs, incidents seemed to have *preceded* AEs in 55.6% and *followed* AEs in 44.4%. For example, one haemorrhage AE was preceded by a heparin overdose incident, while another was followed by a blood transfusion incident. Looking at the most common incident and AE types: medication incidents mostly seemed to have preceded

Table 3. Co-occurrence and presence of relations per adverse event and incidents type.*

Type of adverse event	***Co-occurring with incident(s) in admission*** 1973 (100.0) n (column %)		***Related to co-occurring incident(s)*** 262 (13.3) n (row %)		***Unrelated to co-occurring incident(s)*** 1711 (86.7) n (row %)	
Inflammation/infection	587	(29.8)	63	(10.7)	524	(89.3)
Functional disorder	384	(19.5)	46	(12.0)	338	(88.0)
Symptom without diagnosis	140	(7.1)	35	(25.0)	105	(75.0)
Bleeding/haematoma	141	(7.1)	11	(7.8)	130	(92.2)
Other/non-specified	121	(6.1)	18	(14.9)	103	(85.1)
Psychological disturbance	118	(6.0)	35	(29.7)	83	(70.3)
Accumulation of body fluids	94	(4.8)	11	(11.7)	83	(88.3)
Thrombosis/embolus	84	(4.3)	14	(16.7)	70	(83.3)
Abnormal wound healing	74	(3.8)	4	(5.4)	70	(94.6)
Injury by mechanical/physical-chemical disturbance	68	(3.4)	11	(16.2)	57	(83.8)
Rejection/allergy/immunological reaction	41	(2.1)	8	(19.5)	33	(80.5)
Pressure sore	40	(2.0)	4	(10.0)	36	(90.0)
Necrosis/infarction	32	(1.6)	1	(3.1)	31	(96.9)
Shock	20	(1.0)	1	(5.0)	19	(95.0)
Ischaemia	12	(0.6)	0	(0.0)	12	(100.0)
Procedure with unintended substandard outcome	10	(0.5)	0	(0.0)	10	(100.0)
Fistula	7	(0.4)	0	(0.0)	7	(100.0)
Type of incident	***Co-occurring with AE(s) in admission*** 1138 (100.0) n (column %)		***Related to co-occurring AE(s)*** 290 (25.5) n (row %)		**Unrelated to co-occurring AE(s)** 848 (74.5) n (row %)	
Medication/intravenous fluids	719	(63.2)	164	(22.8)	555	(77.2)
Clinical process/procedure	148	(13.0)	45	(30.4)	103	(69.6)
Patient accidents	67	(5.9)	46	(68.7)	21	(31.3)
Documentation	54	(4.7)	6	(11.1)	48	(88.9)
Clinical administration	47	(4.1)	6	(12.8)	41	(87.2)
Medical device/equipment	41	(3.6)	14	(34.1)	27	(65.9)
Resources/organisational management	31	(2.7)	5	(16.1)	26	(83.9)
Blood (products)	17	(1.5)	3	(17.6)	14	(82.4)
Unclear	5	(0.4)	1	(20.0)	4	(80.0)
Nutrition	5	(0.4)	0	(0.0)	5	(100.0)
Infrastructure/building	3	(0.3)	0	(0.0)	3	(100.0)
Staff/patient behaviour	1	(0.2)	0	(0.0)	1	(100.0)

AE, adverse event.

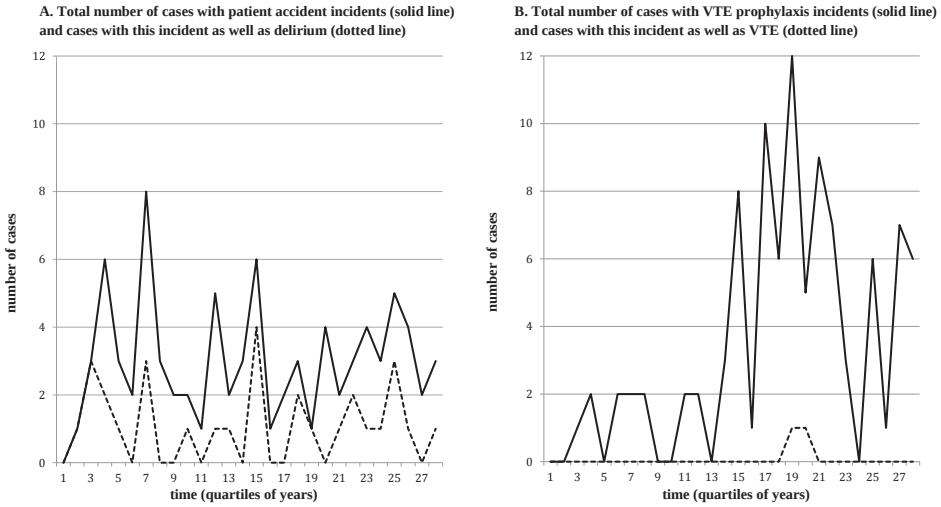
* Descriptive statistics are at the AE/incident level, not at the patient level. One admission can have more than one AE and/or incident type.

related AEs (61.6% of 164), and incidents related to infections mostly seemed to have followed these AEs (65.1% of 63).

For the a-priori selected themes, delirium was more common among cases with than without incidents of the 'patient accident' type (35.7% vs 1.6%; x^2=594; p<.001). This pattern of frequent co-occurrence was also visible over time (Figure 2, A). In general, incidents of

the 'patient accident' type mostly seemed to have followed rather than preceded related AEs (65.2% of 46). A different pattern was observed for VTE and VTE prophylaxis. Only 2 of the 97 cases with VTE prophylaxis incidents also had VTE in the same admission (both preceding AE). These 2 cases occurred after a strong increase of VTE prophylaxis incidents (Figure 2, B), while overall VTE reporting rate remained stable (both before and after incident increase: mean 0.3% of cases per quartile).

Figure 2. Selected clinical themes: co-occurrence of specific incidents and adverse events in admissiosn over time.



VTE, venous thromboembolism.

Cascades

Overall, AE cascades (≥3 AEs) were present for 845 admissions, of which 31.2% also had incidents and 0.2% had filed complaints. Admissions with incidents and AEs more commonly had AE cascades than admissions with only AEs (36.2% vs 14.1%; x^2=208; p<.001) (Table 2). This difference remained in multivariable analysis, adjusted for patient characteristics, both for cases with related incidents (OR 5.7; 95% CI 4.3 to 7.4) and cases with only seemingly unrelated incidents (OR 2.0; 95% CI 1.6 to 2.5). AE cascades were just as common among cases with only incidents following related AEs as in cases with incidents preceding AEs (52.0% vs 53.0%; x^2=.023; p=.880). Cases with AE cascades were more likely to have a long length of stay (OR 5.1; 95% CI 4.1 to 6.4), but no differences were observed for risk of readmission (OR 0.9; 95% CI 0.7 to 1.1). For cases with wound infections, having an incident strongly increased the risk of an AE cascade (55.4% vs. 18.8%; p<.001). This applied to patients with related incidents (OR 14.0; 95% CI 5.7 to 34.4) and those with only seemingly unrelated incidents (OR 3.1; 95% CI 1.7 to 5.6). Incident co-occurrence did not increase risk of AE cascades in cases with

anastomotic leakage (OR 1.4; 95% CI 0.5 to 3.6), among which more than half of the patients had AE cascades, both those with incidents (65.5%) and without (56.9%).

DISCUSSION

This study addressed patient-level relations between incidents, AEs and complaints by linking routinely collected data from independent systems. Most patients who filed complaints had no incidents or AEs and addressed relationship problems, whereas complaints for admissions with incidents and/or AEs mostly concerned quality and safety issues. Among admissions with co-occurring incidents and AEs, clinical relations between these events were identified in approximately 1 of 3 admissions. In terms of sequence, incidents seemed to have *preceded* related AEs in 55.6% and *followed* AEs in 44.4% of the clinically related incident/AE pairs. Overall, patients with incidents more commonly had AEs and AE cascades than patients without incidents, regardless of whether these AEs seemed clinically related or in what sequence. These findings demonstrate that although separate systems collect different signals from the same patient journey, these have relations at the patient level and should therefore be interpreted in relation to each other to obtain more comprehensive and detailed information for improvement efforts.

Breaking down the silos

Previous studies encouraged hospitals to use more than one method to collect data on quality and safety because each method provides complementary information, previously compared to the fable of the blind men and the elephant.[1,3,21] Over the years, various systems to collect quality and safety data, such as incidents, AEs and complaints, have been implemented in different periods and isolated from each other.[22] Consequently, co-occurrence cannot be evaluated and relations between events may remain obscured, such as cascades or clusters of seemingly unrelated events. While both incident and AE data (collected through reporting or record review) may be used to reveal suboptimal processes that cause harm, only linkage of their data allows an approach looking at co-occurrence and how initial harm may trigger further process problems and cascades of events. Integration of these systems would also connect perspectives of nurses, physicians and patients and may reveal unreported problems, as illustrated by our finding that incident reports revealed patient complaints not otherwise reported. Complaints are a particularly under-used source of information for improvement because they mostly remain completely separated from quality and safety data.[20,22,23] This study indicates that this may be a missed opportunity because complaints from patients with incidents and/or AEs specifically provided information on quality and safety from the patient perspective.

Ability to respond

Although incident reporting is known to be very poor at detecting AEs,[2,3] incident reports are unique stories from the sharp end that may reveal local system hazards before harm is inflicted.[24] Previous authors underlined that reports of near misses (ie, unharmful incidents) can be used to study resilience of healthcare processes because these indicate successful responses to potentially harmful situations.[14,25,26] Equally important is the capacity to respond to harm once inflicted, preventing that (responses to) initial AEs send patients 'out of the frying pan into the fire', which bears similarity to the concept of 'failure to rescue'.[27,28] Patient-level data linkage allows further study of critical elements of safety,[29] namely the ability to anticipate, respond and adapt to difficulties, such as increased vulnerability and complexity of patients with AEs and incidents. This vulnerability and complexity was particularly illustrated in this study by the increased risk of AE cascades for patients with wound infections who also experienced incidents. The obtained insights can be used to enhance these abilities, which responds to calls for a more proactive and preventive approach to patient safety.[30]

Practical implications

Integration of quality and safety systems will require investments that may differ per institution, depending on whether information is available in a digital format and (can be) linked to corresponding admissions. For example, not all hospitals have digitalised patient complaints.[22] Hospitals could start by providing a clear overview of a patient's AEs and incidents in the medical record (integrating safety systems into electronic records), because this may support the ability of (rotating) staff to anticipate future problems for these patients. In addition, patients with both incidents and AEs could be sampled for higher priority in-depth analysis or discussion at team meetings, eg, morbidity and mortality conferences. These learning reviews should additionally address the team's response to these events and any patient complaints, which means that complaints data should be made accessible. This approach honours the principle that it is more valuable to thoroughly analyse a small number of events than to superficially study large volumes of data.[8,31] Another practical implication would be to consider expanding the focus of record review to what happened *after* AEs (eg, whether the AE triggered incidents), and to encourage incident reporters to address what happened *before* incidents (eg, whether the incident was preceded by AEs), in order to identify chains of events.

Strengths and limitations

A strength of this study is that it is the first in its kind to study patient-level relations between different types of quality and safety data routinely collected over several years. A study limitation is that underreporting may have affected incident rates. This may particularly apply to the years before electronic reporting after which incident rates doubled, as also observed elsewhere.[1,32] AE rates were more stable and have been demonstrated to be similar to those obtained through record review.[18] Moreover, incident, AE and complaint rates closely resembled

those in other studies.[12,32–35] We acknowledge that the AE cascade definition is arbitrary and that it remains unclear how these events are related, but this variable was used to reflect cases progressing from bad to worse, which likely resonates with clinicians. Accurate data on the exact timing of events is required to examine chains of events more closely. The finding of longer length of stay for patients with AEs/incidents should be interpreted with caution as this could also reflect greater complexity of these cases, which could have occurred regardless of incidents/AEs. Similarly, that cases with incidents were at increased risk of unrelated AEs may reflect their greater complexity for which we could not fully adjust. Although clinical relations were assessed by clinician-researchers, this remains subjective similar to record review studies.[36,37] Even though generalisability is an important limitation of any single centre study, this study presents more general messages potentially relevant for other institutions. The relations between events demonstrated in this study likely reflect a more universal underlying process of increased patient vulnerability and complexity. Therefore, these findings could encourage hospitals with other definitions or methods (eg, record review) to integrate available incident, AE and complaint data to obtain rich information that helps envision the bigger picture of patient safety.

Future directions

Future research is needed on clusters of seemingly unrelated incidents and AEs, and the impact of incidents after initial AEs. These studies could provide guidance for clinical practice by identifying what types of events warrant more vigilance in monitoring and management to prevent a negative cascade of events. Ideally, hospitals would use a linked registry to detect early warnings before (more) patients are harmed, but methods still need to be developed and validated. Another important extension could be to use integrated data from various sources to study particularly 'safe' teams or processes in order to increase understanding of why things go *right*[38,39] and to seek exemplary behaviour and solutions that are already present within the clinical community.[40,41] With this study, we hope to inspire more research with patient-level linkage of currently available data in other settings and with other types of data, such as patient-reported outcome or experience data.

Conclusions

This study shows how patient-level linkage of incident, AE and complaint data can reveal relations that otherwise remain obscured, such as incidents emerging in the context of prior AEs or triggering AE cascades, even for seemingly unrelated events. As we have come to appreciate that the various data systems in hospitals offer different 'windows onto the system',[8] we should start integrating these for a more 'panoramic' view on healthcare quality and safety.

Acknowledgment

We like to show our gratitude to all clinicians involved in the data gathering over the years.

What is already known on this subject:

- Incident, adverse event (AE), and patient complaints data are typically collected separately and used in isolation, revealing different types of safety issues.
- Incident reporting is known to be poor at detecting AEs, which are commonly detected using record review.

What this study adds:

- Linkage of incident, adverse event (AE) and complaint data allows a more comprehensive analysis of relations between events in the same admissions, such as that incidents trigger (cascades of) AEs but also follow initial AEs.
- While most complaints were filed for admissions without incidents or AEs, complaints for cases with incidents and/or AEs mostly addressed quality and safety issues, providing an additional resource for quality improvement.
- Patients with incidents were at increased risk of (cascades of) AEs, regardless of whether these seemed clinically related and in what sequence, which likely reflects that these events increase underlying vulnerability and complexity in patients.

REFERENCES

1. Levtzion-Korach O, Frankel A, Alcalai H, *et al.* Integrating Incident Data from Five Reporting Systems to Assess Patient Safety: Making Sense of the Elephant. *Jt Comm J Qual Patient Saf* 2010;36:402–10. doi:10.1016/S1553-7250(10)36059-4
2. Sari A, Sheldon T, Cracknell A, *et al.* Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *Br Med J* 2007;334:79. doi:10.1136/bmj.39031.507153.AE
3. Olsen S, Neale G, Schwab K, *et al.* Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place. *Qual Saf Heal Care* 2007;16:40–4. doi:10.1136/qshc.2005.017616
4. Christiaans-Dingelhoff I, Smits M, Zwaan L, *et al.* To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports? *BMC Health Serv Res* 2011;11:49. doi:10.1186/1472-6963-11-49
5. de Feijter JM, de Grave WS, Muijtjens AM, *et al.* A comprehensive overview of medical error in hospitals using incident-reporting systems, patient complaints and chart review of inpatient deaths. *PLoS One* 2012. doi:10.1371/journal.pone.0031125
6. Michel P, Quenon JL, de Sarasqueta AM, *et al.* Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *BMJ* 2004;328:199. doi:10.1136/bmj.328.7433.199
7. Howell A-M, Burns EM, Hull L, *et al.* International recommendations for national patient safety incident reporting systems: an expert Delphi consensus-building process. *BMJ Qual Saf* 2017;26:150–63. doi:10.1136/bmjqs-2015-004456
8. Vincent CA. Analysis of clinical incidents: a window on the system not a search for root causes. *Qual Saf Heal Care* 2004;13:242–3. doi:10.1136/qshc.2004.010454
9. Macrae C. The problem with incident reporting. *BMJ Qual Saf* 2016;25:71–5. doi:10.1136/bmjqs-2015-004732
10. Deeny SR, Steventon A. Making sense of the shadows: priorities for creating a learning healthcare system based on routinely collected data. *BMJ Qual Saf* 2015;24:505–15. doi:10.1136/bmjqs-2015-004278
11. Rowin EJ, Lucier D, Pauker SG, *et al.* Does Error and Adverse Event Reporting by Physicians and Nurses Differ? *Jt Comm J Qual Patient Saf* 2008;34:537–45.
12. Bismark MM, Brennan T, Paterson RJ, *et al.* Relationship between complaints and quality of care in New Zealand: a descriptive analysis of complainants and non-complainants following adverse events. *Qual Saf Health Care* 2006;15:17–22. doi:10.1136/qshc.2005.015743
13. World Alliance for Patient Safety. WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. Geneva: World Health Organization: 2005. http://apps.who.int/iris/bitstream/10665/69797/1/WHO-EIP-SPO-QPS-05.3-eng.pdf (accessed 18 Sept 2017).
14. Hewitt TA, Chreim S. Fix and forget or fix and report: a qualitative study of tensions at the front line of incident reporting. *BMJ Qual Saf* 2015;24:303–10. doi:10.1136/bmjqs-2014-003279
15. Wagner C, Van der Wal G. Voor een goed begrip-bevordering van de patiëntveiligheid vraagt om heldere definities [in Dutch]. *Med Contact* 2005;47:1888–91.
16. World Health Organization. The Conceptual Framework for the International Classification for Patient Safety. Version 1.1. Final Technical Report. 2009. http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf (Accessed 1 Sep 2017)
17. Kievit J, Krukerink M, Marang-van de Mheen PJ. Surgical adverse outcome reporting as part of routine clinical care. *Qual Saf Health Care* 2010;19:e20. doi:10.1136/qshc.2008.027458

18. Marang-van de Mheen PJ, van Hanegem N, Kievit J. Effectiveness of routine reporting to identify minor and serious adverse outcomes in surgical patients. *Qual Saf Health Care* 2005;14:378–82. doi:10.1136/qshc.2004.013250
19. Marang-van de Mheen PJ, Stadlander MC, Kievit J. Adverse outcomes in surgical patients: implementation of a nationwide reporting system. *Qual Saf Health Care* 2006;15:320–4. doi:10.1136/qshc.2005.016220
20. Gillespie A, Reader TW. The Healthcare Complaints Analysis Tool: development and reliability testing of a method for service monitoring and organisational learning. *BMJ Qual Saf* 2016;25:937–46. doi:10.1136/bmjqs-2015-004596
21. Shojania K. The elephant of patient safety What you see depends on how you look. *Jt Comm J Qual Patient Saf* 2010;36:399–401.
22. de Vos MS, Hamming JF, Marang-van de Mheen PJ. The problem with using patient complaints for improvement. *BMJ Qual Saf* 2018;27:758-762. doi:10.1136/bmjqs-2017-007463
23. Gallagher TH, Mazor KM. Taking complaints seriously: using the patient safety lens. *BMJ Qual Saf* 2015;24:352–5. doi:10.1136/bmjqs-2015-004337
24. Pham JC, Girard T, Pronovost PJ. What to do with healthcare Incident Reporting Systems. *J Public Heal Res* 2013;2:27. doi:10.4081/jphr.2013.e27
25. Kessels-Habraken M, Van der Schaaf T, De Jonge J, *et al.* Defining near misses: Towards a sharpened definition based on empirical data about error handling processes. *Soc Sci Med* 2010;70:1301–8.
26. Franklin BD, Panesar SS, Vincent C, *et al.* Identifying systems failures in the pathway to a catastrophic event: An analysis of national incident report data relating to vinca alkaloids. *BMJ Qual Saf* 2014;23:765–72. doi:10.1136/bmjqs-2013-002572
27. Silber J, Rosenbaum P, Schwartz J, *et al.* Evaluation of the Complication Rate as a Measure of Quality of Care in Coronary Artery Bypass Graft Surgery. *JAMA* 1995;275:317–23. doi:10.1001/jama.1995.03530040045039
28. Moriarty J, Finnie D, Johnson M, *et al.* Do pre-existing complications affect the failure to rescue quality measures? *BMJ Qual Saf* 2010;19:65–8.
29. Vincent C, Burnett S, Carthey J. The measurement and monitoring of safety - drawing together academic evidence and practical experience to produce a framework for safety measurement and montioring. London, UK: 2013.
30. Feeley D. Six Resolutions to Reboot Patient Safety. Institute for Healthcare Improvement. 2017. http://www.ihi.org/communities/blogs/_layouts/15/ihi/community/blog/ItemView.aspx?List=7d1126ec-8f63-4a3b-9926-c44ea3036813&ID=365&Web=1e880535-d855-4727-a8c1-27ee672f115d (Accessed 1 Sep 2017).
31. Vincent C. Incident reporting and patient safety. *BMJ* 2007;334:51. doi:10.1136/bmj.39063.645532.BE
32. Milch CE, Salem DN, Pauker SG, *et al.* Voluntary electronic reporting of medical errors and adverse events: An analysis of 92,547 reports from 26 acute care hospitals. *J Gen Intern Med* 2006;21:165–70. doi:10.1111/j.1525-1497.2006.00322.x
33. Wang Y, Eldridge N, Metersky ML, *et al.* National Trends in Patient Safety for Four Common Conditions, 2005–2011. *N Engl J Med* 2014;370:341–51. doi:10.1056/NEJMsa1300991
34. Marang-van de Mheen PJ, Hollander EJF, Kievit J. Effects of study methodology on adverse outcome occurrence and mortality. *Int J Qual Heal Care* 2007;19:399–406. doi:10.1093/intqhc/mzm039
35. Taylor DM, Wolfe RS, Cameron PA. Analysis of complaints lodged by patients attending Victorian hospitals, 1997-2001. *Med J Aust* 2004;181:31–5.
36. Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer. *JAMA* 2001;286:415–20. doi:10.1001/jama.286.4.415

37. Hogan H. The problem with preventable deaths. *BMJ Qual Saf* 2016;25:320–3. doi:10.1136/bmjqs-2015-004983
38. Hollnagel E, Wears R, Braithwaite J. From Safety-I to Safety-II: A White Paper. Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia: 2015. https://resilienthealthcare.net/wp-content/uploads/2018/05/WhitePaperFinal.pdf(Accessed 9 Feb 2017)
39. Braithwaite J, Wears RL, Hollnagel E. Resilient health care: Turning patient safety on its head. *Int J Qual Heal Care* 2015;27:418–20. doi:10.1093/intqhc/mzv063
40. Lawton R, Taylor N, Clay-Williams R, *et al.* Positive deviance: a different approach to achieving patient safety. *BMJ Qual Saf* 2014;23:880-883. doi:10.1136/bmjqs-2014-003115
41. Baxter R, Taylor N, Kellar I, *et al.* What methods are used to apply positive deviance within healthcare organisations? A systematic review. *BMJ Qual Saf* 2016;25:190-201. doi:10.1136/bmjqs-2015-004386

Chapter 6

The problem with using patient complaints for improvement

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'The Problem with…' series covers controversial topics related to efforts to improve healthcare quality, including widely recommended, but deceptively difficult strategies for improvement and pervasive problems that seem to resist solution.

THE PROBLEM WITH USING PATIENT COMPLAINTS FOR IMPROVEMENT

Patients can voice their concerns in letters of complaint, written to the hospital or a regulatory body. By doing so, patients may want to express disappointment with some aspect of care and/or may want to urge and help the hospital to improve the care delivered to patients in the future.[1-4] Healthcare providers and managers are committed, and ethically obliged, to continuously improve healthcare as well as to listen and act on their patients' concerns. Still, patient complaints are hardly used for quality improvement (QI),[5,6] which seems a missed opportunity to learn from the patient's perspective. Using patient complaints (i.e., the content of formal complaint letters received by hospitals) as an actual tool for improvement is, however, hampered by various problems related to this source of information. This article will discuss these problems, which might explain why patient complaints often remain so absent from systematic efforts to improve healthcare.

COMPLAINTS ARE HANDLED IN ISOLATION

The first barriers to using complaints for systematic improvement are introduced by the ways in which complaints are handled in hospitals.

Physical separation

Complaints handling is traditionally located near hospital lawyers, patient advocates or guest services, rather than the later-developed quality and safety departments. It may also be difficult to reference complaints data for QI purposes as complaints are often archived in binders, sorted on patient or physician names, rather than in accessible digital databases. This separation of complaints from QI practices precludes this information from being used, for example, to gain insights into patient-centeredness or continuity of care.[6]

Case-by-case handling

Moreover, while most hospitals have installed systems to learn from adverse events and incidents, systems to learn from complaints are lacking.[7] The ability to learn from complaints is particularly limited by the one-by-one approach to complaints. On receiving a complaint, most hospitals notify the involved providers, who (help to) write a response.[8-10] While important for restoring the provider-patient relationship, this approach also treats complaints as isolated issues between individual providers and patients. One negative effect of this is that providers could be given the feeling that they are individually responsible for the whole of

the negative patient experience, inducing feelings of shame and guilt that hamper learning.[11] Another result is that the case seems 'closed' once a response is sent, which fails to trigger a deeper investigation, and to share the learning within the team, department or hospital. The handling process may be finished when the complaint and response letter are archived, but this does not necessarily mean that the complaint's problem has been resolved. It will remain difficult to define or determine when exactly a complaint is resolved, but complaints handling should be seen as the beginning of a process to gain a deeper understanding of the patient's concerns and how the issues could be addressed, rather than the end of a service provided to patients.

COMPLAINTS ARE COMPLEX STORIES

Use of complaints to develop improvement requires identifying the issues that underlie the complaint, as well as identifying adequate targets and strategies for improvement. These processes are challenged by various difficulties related to distinct features of patient complaints.

Elusive source of information

As complaints often result from cascades of problems until 'the straw that broke the camel's back',[12] there will often be various issues and sources of frustration that contributed to the patient's negative experience. Identifying the exact underlying problems can be remarkably difficult. Complaint letters can be difficult to read as they are mostly unstandardised, unstructured and emotive,[13] as well as written by patients and families with varying educational backgrounds. Moreover, complainants may have interpreted certain events more harshly in a context of cumulative hurt and frustration,[9] and may focus on subjective aspects of care, such as compassion, while leaving other important contributory factors or problems undiscussed.[13] This process is further challenged by bias on the receiving end, as it can be difficult to interpret complaints in a non-judgemental, unbiased manner, particularly when one's skills and attitudes are criticised.[13] A survey among physicians showed that one in three did not consider complainants 'normal people', and this was even more so among physicians who had experienced complaints.[14] This raises the question whether we should rely on individual providers to draw lessons from complaints. At the same time, close involvement of healthcare professionals is essential to provide medical and context knowledge as well as for frontline engagement, which are required for learning and improvement processes. Both receptivity to complaints and patient's willingness to report complaints might benefit from using a term such as 'patient feedback' instead of a term that is synonymous with 'whining' and 'moaning' in the dictionary.

Coding tools do not identify underlying problems

While methods for standardised analysis of complaints seem beneficial to structure and categorise the problems addressed, this process is first of all complicated by the complexity of

these letters, as described above. Moreover, coding strategies used by these methods may pose problems when trying to use complaints for QI. A recently validated tool is the Healthcare Complaints Analysis Tool (HCAT), which was developed using taxonomies from 59 previous studies.[6,13] This method requires taking complaint letters at face value, strictly adhering to the words used in the text. It is understandable that the method does not allow personal interpretation of the letter's content, but this type of coding may therefore point to different issues than in-depth investigations of the situation and context would. For example, if a complainant writes that he received the wrong treatment, this will be coded as 'clinical', while in fact the underlying problem may be related to insufficient explanation and hence 'communication'. While contextual information may be available in the provider's response letter, these are not taken into account in these analyses.

DIFFICULTIES IDENTIFYING THE IMPROVEMENT STRATEGY AND TARGET GROUP

Even if the problems underlying a complaint have been accurately identified, improvement efforts are further challenged by the need to determine whether the problem is individual or reflects system issues, and whether this is an isolated or recurring problem. These distinctions are important as they will impact what improvement strategies and target groups are adequate in response to the complaint.

Healthcare is a team effort

It is not easy to determine whether problems that triggered a complaint are individual-oriented or system-oriented, as relationships between individual-related and system-related causes of problems are complex and difficult to separate.[15,16] Some complaints about individual behaviour may be related to underlying system problems. To illustrate, complaints about a brusque doctor or a nurse not responding to call bells in a timely manner could reflect the typical behaviour of that clinician but could also reflect problems with problematic workload or conflicting expectations of staff. A tendency to view the individual provider as the problem that needs fixing fails to identify underlying system factors[17] and could also unnecessarily damage healthcare professionals. While it has been shown that a small number of physicians account for a large proportion of complaints,[18] we cannot rule out whether these providers were more prone to complaints due to a larger volume of patients or more difficult patients,[16,19] such as patients with a greater risk of complications and hence of complaints.[20] The use of complaint rates as a metric to identify 'bad doctors' would therefore, as most tests, render false positives, falsely accusing colleagues of incompetence. Moreover, it seems unrealistic to regard patient complaints as criticisms of individual providers. Modern healthcare is provided by many hands,[21] and providers are part of larger teams and systems. It has been estimated that medical and surgical patients may see up to 44 and 75 different health professionals during their hospitalisation.[22] Accordingly, complaint letters frequently address more than one issue,[6]

related to providers of several disciplines (including administrative staff), departments or institutions. As a result, it often remains unclear what the exact target group for improvement should be.

Estimating the size of the iceberg

Another distinction that should be made is whether the problem addressed in the complaint was an isolated occurrence or a recurring issue, as we would not want to make changes to our systems on the basis of very specific, rare events. Such corrective actions may also harm our ability to perform well, for example by increasing complexity. It is logical that a recurring problem would require a different response than a single 'mistake', but the difficulty lies in (determining who is responsible for) making these judgements, as also discussed in Just Culture theory.[23] Unfortunately, we cannot rely on complaint rates to distinguish isolated from recurring problems, as the likelihood that a problem triggers a complaint is not purely related to the frequency of the underlying problem. In other words, a single complaint may represent only 'the tip of the iceberg' for a problem, but may just as well represent an unfortunate, rare occurrence. In fact, complaints are hetereogenous[5] and relations with underlying problems are complex. One type of complaints may have different underlying problems, requiring different improvement strategies (e.g. discharge complaints can be triggered by communication as well as logistic issues). At the same time, one underlying problem could trigger different complaints (e.g. understaffing triggering complaints about staff behaviour as well as clinical care quality). Without deeper investigation, most complaints may simply trigger clinical or communication skills training.

Infrequent and imperfect data

As complaints are so infrequent overall, with rates from the literature ranging between 0.1-0.9% of all admissions,[20,24,25] it might take a while before issues recur, by which time circumstances and opportunities for improvement may have changed already. Analogous to incident rates,[26,27] these numbers will be affected by many other factors than quality of care, such as patients' access to the complaints process. These features make complaint data unfit for monitoring, limiting our ability to identify when a complaint-based improvement is successful. In addition, some patients may be reluctant to file a formal complaint and more inclined to report their concerns in a patient survey instead. Triangulation of complaints data with data about negative patient experiences, for instance extracted from hospital surveys, may establish sufficient volumes and seems an alternative approach worth considering to facilitate learning from the patient perspective.

FROM ISOLATION TO INTEGRATION

Both the ways in which we handle complaints and a number of distinct features of this source of information, complicate their use as a tool for QI. Advancing insights from the patient

safety movement, such as the systems approach and the Just Culture principles, are yet to be applied to the ways in which we learn from complaints.[5] Relevant lessons from incident reporting in healthcare include that we should remain wary of 'collecting too much and doing too little' and view anecdotal data as triggers for participative learning rather than as useful data for quantitative analysis.[26] As proposed by Gallagher and Mazor,[5] complaints should be viewed through the patient safety rather than risk management lens, triggering systematic investigations and efforts to prevent recurrences. Specifically, we propose that complaints are used as triggers for team learning and further in-depth inquiry with other quality and safety data.

Using complaints as triggers

As caring for patients is a team effort, learning from patients' complaints should equally be a collaborative process. Such an approach underlines that 'a complaint against one of us is a complaint against us all' and encourages sharing the learning with colleagues. This would require transforming complaints handling from a service provided to patients, where the learning remains with the responding clinician, into a joint effort of clinician teams and QI staff. For example, complaints could receive a more prominent role in existing learning practices, such as morbidity and mortality conferences. This would encourage discussing the patient perspective as well as soft skills, such as communication or empathy, at these meetings. These meetings could also provide a forum for peer support, and peer feedback, which has been demonstrated to reduce complaint rates of individual providers.[28] These discussions may also help to determine whether problems addressed in complaints are recognised as recurring problems. Yet, some colleagues may be reluctant to report problems with a fellow clinician.[29,30,31] Therefore, additional investigation will likely be required to assess whether problems raised in complaints are also reflected in other available sources of information, such as interviews with complainants and providers, direct observation of care[17] or review of response letters and medical records. Moreover, hospitals could use triangulation with other data from the clinician or patient perspective, such as quantitative outcome or patient experience data (e.g., National Surgical Quality Improvement Program [NSQIP] or Hospital Consumer Assessment of Healthcare Providers and Systems [HCAHPS]), but even then, it will remain extremely difficult to identify and solve the actual system problems, a process that requires substantial work and investments.[17]

To conclude, there are various barriers that hamper using patient complaints to develop improvements. Yet complaints could be taken out of isolation and more closely connected to other QI processes. The associated costs and efforts will vary per hospital, as, for example, not all hospitals have digitalised complaints[8,32,33] or routinely collect patient experience data. Hospitals could start by using complaints as triggers for participative learning in teams and further in-depth inquiry with other available QI data. This would address at least part of

the various challenges described in this paper, and allow to share the learning from patient complaints within teams and institutions.

- Patient complaints represent patients' perspective on healthcare, but are hardly used for improvement, which is likely influenced by various problems related to this specific source of information.
- Complaints are handled in isolation on a case-by-case level, which fails to trigger deeper learning or investigation and to align with improvement and learning practices.
- Complaint letters are an especially complex and elusive information source with data of low and unreliable volume, which challenges efforts to categorise and code these data, and thereby complicates identifying underlying problems and adequate improvements.
- These features create difficulties to determine whether problems addressed in complaints are individual-related or system-related, and whether these reflect an isolated or recurring issue, which all have implications for quality improvement (QI) efforts.
- Given these problems, complaints should be used as a starting point for collaborative learning and used as triggers for further inquiry with other QI data, such as patient experience data.

REFERENCES

1. Friele RD, Sluijs EM. Patient expectations of fair complaint handling in hospitals: empirical data. *BMC Health Serv Res* 2006;6:106. doi:10.1186/1472-6963-6-106.
2. Bark P, Vincent C, Jones A, Savory J. Clinical complaints: a means of improving quality of care. *Qual Health Care* 1994;3:123-132.
3. Bismark M, Dauer E, Paterson R, et al. Accountability sought by patients following adverse events from medical care: the New Zealand experience. *CMAJ* 2006;175:889-894.
4. Bouwman R, Bomhoff M, Robben P, et al. Patients' perspectives on the role of their complaints in the regulatory process. *Health Expect* 2016;19:483-496.
5. Gallagher TH, Mazor KM. Taking complaints seriously: using the patient safety lens. *BMJ Qual Saf* 2015;24:352-355. doi:10.1136/bmjqs-2015-004337.
6. Gillespie A, Reader TW. The Healthcare Complaints Analysis Tool: development and reliability testing of a method for service monitoring and organisational learning. *BMJ Qual Saf* 2016;25:937-946. doi:10.1136/bmjqs-2015-004596.
7. Parliamentary and Health Service Ombudsman. *A Review into the Quality of NHS Complaints Investigations Where Serious or Avoidable Harm Has Been Alleged*; 2015. https://www.ombudsman.org.uk/sites/default/files/A_review_into_the_quality_of_NHS_complaints_investigations_where_serious_or_avoidable_harm_has_been_alleged.pdf (Accessed 25 July 2017).
8. Levin C, Hopkins J. Creating a Patient Complaint Capture and Resolution Process to Incorporate Best Practices for Patient-Centered Representation. *Jt Comm J Qual Patient Saf* 2014;40:484-492.
9. ECRI Institute. Managing patient complaints and grievances. *Healthc Risk Control* 2016 https://www.ecri.org/components/HRC/Pages/PtSup1.aspx (Accessed 1 Aug 2017).
10. Clarke Willmott. *An Essential Guide to NHS Complaints*; 2015. https://www.clarkewillmott.com/wp-content/uploads/2015/07/NHS-Complaints-fact-sheet.pdf (Accessed 1 Aug 2017).
11. Dekker SWA, Leveson NG. The systems approach to medicine: controversy and misconceptions. *BMJ Qual Saf* 2015;24:7-9. doi:10.1136/bmjqs-2014-003106.
12. Montini T, Noble AA, Stelfox HT. Content analysis of patient complaints. *Int J Qual Heal Care* 2008;20:412-420. doi:10.1093/intqhc/mzn041.
13. Reader TW, Gillespie A, Roberts J. Patient complaints in healthcare systems: a systematic review and coding taxonomy. *BMJ Qual Saf* 2014;23:678-689. doi:10.1136/bmjqs-2013-002437.
14. Cunningham W. New Zealand doctors' attitudes towards the complaints and disciplinary process. *NZ Med J* 2004;117:1-9.
15. Mello M, Studdert D. Deconstructing negligence: the role of individual and system factors in causing medical injuries. *Georg Law J* 2008;96:599-623.
16. Spittal MJ, Bismark MM, Studdert DM. The PRONE score: an algorithm for predicting doctors' risks of formal patient complaints using routinely collected administrative data. *BMJ Qual Saf* 2015;24:360-368. doi:10.1136/bmjqs-2014-003834.
17. Trbovich P, Shojania KG. Root-cause analysis: swatting at mosquitoes versus draining the swamp. *BMJ Qual Saf* 2017;26:350-353. doi:10.1136/bmjqs-2016-006229.
18. Bismark MM, Spittal MJ, Gurrin LC, Ward M, Studdert DM. Identification of doctors at risk of recurrent complaints: a national study of healthcare complaints in Australia. *BMJ Qual Saf* 2013;22:534-540. doi:10.1136/bmjqs-2012-001691.
19. Obermair A, Janda M, Gebksi V. Identification of doctors at risk of recurrent complaints: a national study of healthcare complaints in Australia. *BMJ Qual Saf* 2013;22:878. doi:10.1136/bmjqs-2012-001691.

20. Murff HJ. Relationship between patient complaints and surgical complications. *Qual Saf Health Care* 2006;15:13-16. doi:10.1136/qshc.2005.013847.
21. Dixon-Woods M, Pronovost PJ. Patient safety and the problem of many hands. *BMJ Qual Saf*. 2016;25:485-488. doi:10.1136/bmjqs-2016-005232.
22. Whitt N, Harvey R, McLeod G, Child C. How many health professionals does a patient see during an average hospital stay? *NZ Med J*. 2007;120:1-8.
23. Dekker SWA, Hugh TB. A just culture after Mid Staffordshire. *BMJ Qual Saf* 2014;23:356-358. doi:10.1136/bmjqs-2013-002483.
24. Taylor DM, Wolfe RS, Cameron PA. Analysis of complaints lodged by patients attending Victorian hospitals, 1997-2001. *Med J Aust* 2004;181(1):31-35.
25. Bismark MM, Brennan TA, Paterson RJ, Davis PB, Studdert DM. Relationship between complaints and quality of care in New Zealand: a descriptive analysis of complainants and non-complainants following adverse events. *Qual Saf Health Care* 2006;15:17-22. doi:10.1136/qshc.2005.015743.
26. Macrae C. The problem with incident reporting. *BMJ Qual Saf* 2016;25:71-75. doi:10.1136/bmjqs-2015-004732.
27. Howell AM, Burns EM, Bouras G, Donaldson LJ, Athanasiou T, Darzi A. Can patient safety incident reports be used to compare hospital safety? Results from a quantitative analysis of the english national reporting and learning system data. *PLoS One* 2015;10:e0144107. doi:10.1371/journal.pone.0144107.
28. Pichert J, Moore I, Karrass J. An intervention model that promotes accountability: peer messengers and patient/family complaints. *Jt Comm J Qual Patient Saf* 2013;39:435-446.
29. Shojania KG, Dixon-Woods M. "Bad apples": time to redefine as a type of systems problem? *BMJ Qual Saf* 2013;22:528-531. doi:10.1136/bmjqs-2013-002138.
30. Wenink JW, Westert GP, Schoonhoven L, et al. Am I my brother's keeper? A survey of 10 healthcare professions in the Netherlands about experiences with impaired and incompetent colleagues. *BMJ Qual Saf* 2015;24:56-64. doi:10.1136/bmjqs-2014-003068.
31. Mazor K, Roblin DW, Greene SM. Primary care physicians' willingness to disclose oncology errors involving multiple providers to patients. *BMJ Qual Saf* 2016;25:787-795. doi:10.1136/bmjqs-2015-004353.
32. Kroening HL, Kerr B, Bruce J. Patient complaints as predictors of patient safety incidents. *Patient Exp J* 2015;1:94-101.
33. Levtzion-Korach O, Frankel A, Alcalai H, et al. Intergrating incident data from five reporting systems to assess patient safety: making sense of the elephant. *Jt Comm J Qual Patient Saf* 2010;36:402-410. doi:10.1016/S1553-7250(10)36059-4

Chapter 7

The association between complications, incidents and patient experience in surgical care: retrospective linkage of routine patient experience surveys and safety reporting

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ABSTRACT

Background

Linkage of safety data to patient experience data may provide information to improve surgical care. This retrospective observational study aimed to assess associations between complications, incidents, patient-reported problems and overall patient experience.

Methods

Routinely collected data from safety reporting on complications and incidents, and patient-reported problems and experience on the Picker Patient Experience Questionnaire-15, covering 7 experience dimensions, were linked for 4236 surgical inpatients from an academic centre (April 2014-December 2015; 41% response). Associations between complication and/or incident occurrence and patient-reported problems, regarding risk of suboptimal experience (i.e. grade of 1-5 out of 10) were studied using multivariable logistic regression.

Results

Patient-reported problems were associated with occurrence of complications/incidents among patients with suboptimal experiences (OR 2.8; 95% CI: 1.6-4.9), but not among patients with positive experiences (OR 1.0; 95% CI: 0.6-1.5). For each patient experience dimension, presence of patient-reported problems increased risk of suboptimal experience (OR range: 2.7-4.4). Patients with complications or incidents but without patient-reported outcomes were at lower risk of a suboptimal experience than patients without any problems (OR 0.5; 95% CI: 0.3-0.9). Occurrence of complications/incidents only increased risk of suboptimal experience when patients also had problems on 'continuity and transition' or 'respect for patient preferences' dimensions.

Conclusions

Linking safety data to patient experience data can reveal ways to optimize surgical care. Surgical staff seem able to ensure positive patient experiences despite complications or incidents. Increased attention should be paid to respecting patient preferences, and continuity and transition, particularly when complications or incidents occur.

Key words: quality improvement; patient experience; patient safety; complications; incident reporting.

INTRODUCTION

Surgical inpatient care aims to ensure high-quality care and patient safety as well as an optimal experience for patients. There is an increasing amount of information available on patient experience, due to surveys such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)[1] or the National Adult Inpatient Survey.[2] Other means are used to collect data on safety from the perspective of surgical staff, such as reporting systems or record review. Greater insight into the relationship between patient experience and markers of safety, such as complications or incidents (e.g. postoperative hemorrhage, medication error), could help to optimize surgical care and ensure positive patient experiences.

Much remains unknown about the interplay between patient experience and complications or incidents. Previous studies that assessed patient experience in relation to quality and safety outcomes were mostly at the hospital level, and have produced conflicting results in terms of whether an association existed.[3–10] Part of this may be due to the fact that these data are not typically linked at the patient level because of the anonymity of patient surveys. The level of analysis matters because relations observed at the group level (i.e., hospital) are not necessarily the same at the individual level (i.e., patient), which is referred to as 'the ecological fallacy.'[11,12] After all, when hospitals with high patient satisfaction rates also have high-quality outcomes, it cannot be inferred that these two actually occurred in the same individual patients.

Greater insight into these associations is necessary to understand how we could use patient experiences to improve quality of care. Aim of the present study was to examine the association between complications, incidents and patient-reported experiences at the patient level. In comparison to previous studies, this study included more detailed information on patient experience dimensions and timing of survey response to allow for more comprehensive analyses. We hypothesized that patient-level linkage of data on complications, incidents and patient experiences, collected through routine safety reporting by surgical staff and patient surveys, may reveal valuable information to improve surgical inpatient care.

METHODS

This retrospective observational study linked all routinely collected data on admissions, patient experiences, and complications/incidents collected through safety reporting, for surgical inpatients of a Dutch academic hospital.

Patients and definitions

Data for all 6708 surgical inpatients discharged between April 2014 and December 2015 were included. The requirement for ethical approval was waived by the local Ethics Committee (#G17.073) based on the Dutch Medical Research Involving Human Subject Act.

Patient experience survey

'Patient-reported problems' were defined as ≥1 problems reported on any of the 15 items of the Picker Patient Experience Questionnaire (PPE-15) (Appendix 1). This is a validated survey covering seven patients' experience dimensions (Table 1).[13] For local implementation, the survey was translated into Dutch and then back-translated to English according to the customary procedure for translation verification.[14] Presence of a 'problem' is coded dichotomously (0=no, 1=yes) for each of the survey items, which are summarised into a total number of reported problems (maximum: 15). More details on this method can be found elsewhere.[13] Two final questions ask patients for a global rating of patients' hospitalisation (i.e. a 'school grade' on a scale of 1 to 10), and how likely they would recommend this ward to friends and family (4-point scale) (Appendix 1). This recommendation question is identical to the American HCHAPS survey[8] and similar to the 'friends and family test' (6-point scale).[15,16] A positive recommendation was defined as a response of 'definitely' to this question.[8]

The patient experience survey has been routinely distributed among surgical inpatients since March 2014. In the week following discharge, patients receive an invitation letter with a unique access code for the anonymous online survey. For patient above 75 years of age, a paper version of the survey is attached. A reminder/thank you card is sent one week later. Exclusion criteria for survey participation include: deceased patients; patients below 16 years of age; living abroad; transfers to another hospital, psychiatric institution or unknown destination; or a length of stay shorter than three hours. To avoid burdening patients with multiple surveys, invited patients will be blocked in the system for another survey invitation for a period of six months.

Complications and incidents

In this academic centre, complications (e.g. surgical site infection) are routinely reported for all inpatients by treating physicians (or residents under supervision) in electronic health records during patients' hospitalisation and/or at discharge..[17,18] A complication (or 'adverse event') is defined as *any unintended or unwanted event or state, occurring during or following medical care, that is so harmful to a patient's health that adjustment of treatment is required or that permanent damage results*.[17,18] This definition is broader than the commonly used WHO definition (ie, *injury caused by medical management rather than underlying disease*[19]), because it does not exclude complications that may be related to primary disease or comorbidities. This simplifies reporting because interpretation of causality is not required: all complications that require treatment or cause harm are reported. Serious complications are those that require (re)operation or cause irreversible patient harm (or death, but not applicable in this study), which is reflected in reported severity scores.[17,18]

Incidents (e.g. medication error) are voluntarily reported through an electronic hospital-wide reporting system that is accessible for both doctors and nurses, but reports are mostly filed by nurses, similar to many other hospitals.[20,21] A patient safety incident is defined as *an*

Table 1. Items of the PPE-15 questionnaire sorted by related dimensions of patients' experience with numbers referring to the order in the survey.[1]

Dimension	Item and problem identified (item number)
Information and education	Doctors' answers to questions not clear (#1) Nurses' answers to questions not clear (#2)
Coordination of care	Conflicting information from staff (#3)
Physical comfort	Staff did not do enough to control pain (#10)
Emotional support	Anxieties or fears not discussed with doctors (#4) Anxieties or fears not discussed with nurses (#8) Not easy to find someone to talk about concerns (#9)
Respect for patient preferences	Doctors sometimes talked as if I wasn't there (#5) Insufficiently involved in decisions (#6) Not always treated with respect and dignity (#7)
Involvement of family and friends	Family didn't get opportunity to talk to doctor (#11) Family not given information needed to help recovery (#12)
Continuity and transition	Purposes of medicines not explained (#13) Not told about medication side effects (#14) Not told about danger signals to look for at home (#15)
Overall impression	*A. Grade for the admission on this ward (scale 1-10)* *B. Whether the patient would recommend the ward to family and friends if they would needed similar care (4-point Likert scale)*

[1] Adapted from Jenkinson et al, Int J Qual Health Care 2002;14:353-358. Complete questions and response categories are shown in Appendix 1.

event or circumstance which could have resulted, or did result in unnecessary harm to a patient, which follows the commonly used definition of the World Health Organization.[19]

Data and methods

Patient-level admission data were already linked to complication data in the registry and were linked to the separately archived incident data using patient identifiers, incident reporting date and date of admission and discharge. Because the anonymous patient experience data did not include patient identifiers, these were linked to admission data using patient gender, age, admission date and discharge date. Of the 6708 discharged inpatients, 4462 were invited to participate in the survey, of which 4236 (94.9%) could be linked to corresponding admissions as described above. Failed matches were the result of missing values or two or more cases having the same age, gender as well as admission and discharge date. Another potential reason for non-matches was that corrections to the admission data had occurred which had not been made in the separate patient experience database.

Patient experience was categorised according to patients' global ratings. Grades between 1 and 5 were considered 'negative' (equivalent to failing an exam in Dutch schools), grades between 6 and 8 were considered 'neutral' and grades above 8 were considered 'positive'.

This categorisation was supported by prior studies demonstrating that a global rating is the most suitable overarching measure of patient experience.[22,23] Moreover, one of these studies indicated that Dutch patients who give a grade of '6' are best regarded as passives rather than negatives or positives, which is likely related to the fact that a 6 is the threshold for passing a test in the national school grading system.[22]

Statistical analyses

Respondents were compared to patients who were not invited or did not respond on patient characteristics, including age, gender, undergoing surgery or not, American Society of Anaesthesiologists (ASA) physical and emergency status at the first surgical procedure, length of stay, readmission within 30 days, as well as presence of complications/incidents. Among respondents, descriptive statistics were used to describe presence of complications/incidents and patient-reported problems, and distribution of overall patient experiences. Patients with positive experiences were compared to those with a suboptimal (i.e. neutral or negative) experience on patient characteristics as above, as well as the presence and total number of patient-reported problems and serious complications. For categorical variables, χ^2 tests were used, and Mann-Whitney U tests were used for variables age, length of stay and total number of reported problems. Multivariable logistic regression, adjusting for age, gender, undergoing surgery or not and ASA status, was used to examine the association between complications/incidents and patient-reported problems, overall and separately among patients with positive or suboptimal experiences. Similarly, logistic regression was used to examine likelihood of a suboptimal experience for patients with only complications/incidents, only patient-reported problems, or both, in comparison to patients without any problems (i.e., neither patient-reported problems nor complications/incidents), adjusting for patient characteristics as above. Patients with only patient-reported problems were compared to those with also complications/incidents on total number of problems (Mann-Whitney U test) as well as on presence of suboptimal experiences or problems on experience dimensions (χ^2 tests). For each experience dimension (Table 1), multivariable logistic regression was used to examine whether patient-reported problems increased the likelihood of a suboptimal experience, adjusting for age, gender, receiving surgery, ASA status and complication/incident occurrence. In addition, an interaction term was included in these models to study impact of complications/incidents given problems on this dimension (i.e. patient-reported problems for this dimension * complication/incident occurrence). Statistical analyses were conducted using SPSS Statistics (IBM, version 23) with a 0.05 alpha level of significance.

RESULTS

A total of 1748 patients responded to the survey out of the 4236 who were invited and could be linked to admission data (response rate: 41.3%), on average 15 days after discharge (94% of respondents ≤ 30 days). Compared to non-invited or non-responding patients, respondents seemed more often older patients, undergoing elective surgery, with lower ASA status and without readmission, but complication and/or incident occurrence was just as common in both groups (data not shown).

Characteristics of patients with positive and suboptimal experiences

Positive experiences were reported by 687 patients (39.3% of 1748). Suboptimal experiences were reported by 1061 patients, including 1010 (57.8%) neutral experiences and 51 (2.9%) negative experiences (Table 2). Most patients reporting positive experiences (90.2%) would definitely recommend the ward to family and friends, whereas this was 50.2% among patients with neutral experiences, and 0% among patients with negative experiences. Patients with positive experiences had similar characteristics to those with suboptimal experiences, except for patients with positive experiences being older (median age 66.0 vs. 63.0 years; p<.001), and less often having serious complications (1.9% vs. 4.1%; p=.029). Overall, readmission was not associated with patient experience (p=.489). Although patients readmitted *after* survey response (n=80) were just as likely as other respondents to report positive experiences (45.0% vs. 39.0%; p=.285), they were more likely positive than patients who were readmitted *before* responding to the survey about their initial admission (45.0% vs. 27.1%; p=.024).

Table 2. Positive, neutral and negative experiences among patients with and without patient-reported problems and complications/incidents, and number of reported problems per group.

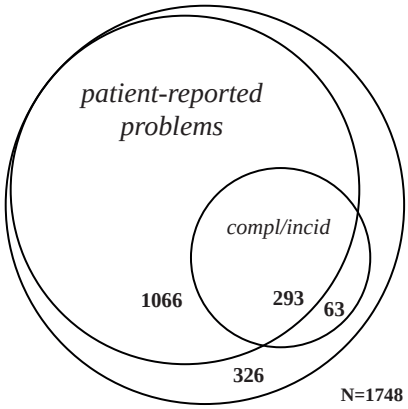
	Overall patient experience						*Number of problems*	
	Positive (n=687, 39.3%)		**Neutral** (n=1010, 57.8%)		**Negative** (n=51, 2.9%)		**Compl/ Incid**	**Patient-reported**
Reported problems								
Only compl/incid (n=63)	48	(76.2)	15	(23.8)	0	-	1.0	-
Only patient (n=1066)	362	(34.0)	666	(62.5)	38	(6.6)	-	2.0
Both (n=293)	78	(26.6)	202	(68.9)	13	(4.4)	1.0	3.0
Neither (n=326)	199	(61.0)	127	(39.0)	0	-	-	-
Number of problems								
Compl/inc	0.0		0.0		0.0			
patient-reported	1.0		3.0		8.0			

Compl/incid, occurrence of complications and/or incidents. Row percentages. Number of problems displays median number of reported problems on the patient experience survey.

Association between patient-reported problems and complications/incidents

Most patients with complications and/or incidents reported problems in the survey (82.3% of 356), but vice versa, only 21.5% of patients reporting problems had complications/incidents (Figure 1). After adjustment for patient characteristics, patients with complications/incidents were more likely to have patient-reported problems than those without (OR 1.5; 95% CI 1.1-2.1). However, when taking overall patient experience into account, the association between complications/incidents and patient-reported problems was only present among patients with suboptimal experiences (OR 2.8; 95% CI 1.6-04.9), and not among those with positive experiences (OR 1.0; 95% CI: 0.6-1.5).

Figure 1. Occurrence of patient-reported problems (total n=1359, 77.4% of 1748) and complications/incidents (total n=356, 20.4%) among patients.



Compl/incid, occurrence of complications and/or incidents.
Numbers in circles refer to the number of cases within that part of the circle (e.g. 1066 cases with only patient-reported problems).

Impact of reported problems on overall experience

Of the 1061 patients with suboptimal experiences, 230 (21.7%) had experienced complications and/or incidents (Table 2). In bivariate analyses, no association was found between complications/incidents and overall patient experience (p=.091), but respondents with patient-reported problems more commonly had suboptimal experiences than those without (67.6% vs. 36.5%; p<.001). In multivariable analysis, adjusting for patient characteristics, risk of suboptimal experience remained greater for cases with patient-reported problems compared to patients without problems or complications/incidents (only patient-reported problems: OR 3.0; 95% CI: 2.3-3.9; both patient-reported problems and complications/incidents: OR 4.4; 95% CI: 3.1 to 6.2). However, remarkably, patients with only complications/incidents were at lower risk of suboptimal experience than patients without problems or complications/incidents (OR 0.5; 95% CI 0.3 to 0.9). This difference disappeared when only serious complications were included (data not shown). Patients with both complications/incidents and patient-reported

Table 3. Distribution of patient-reported problems per dimension and their association with risk of suboptimal experience.

Patients' experience dimension[1]	**Patients reporting problems** n (% of 1748)		**Risk of suboptimal experience** OR (95% CI)
Information and education	342	(19.8)	4.2 (3.1 to 5.8)
Coordination of care	502	(29.1)	2.7 (2.1 to 3.4)
Physical comfort	149	(8.9)	4.4 (2.7 to 7.1)
Emotional support	478	(27.6)	3.7 (2.8 to 4.7)
Respect for patient preferences	691	(39.9)	2.9 (2.3 to 3.6)
Involvement of family	439	(25.4)	4.1 (3.1 to 5.4)
Continuity and transition	897	(52.0)	2.4 (2.0 to 2.9)

[1] Missing values per dimension: information and education (n=19, 1.1%); coordination of care (n=25, 1.4%); physical comfort (n=79, 4.5%); emotional support (n=13, 0.7%); respect for patients preferences (n=17, 1.0%); involvement of family (n=23, 1.3%); continuity and transition (n=23, 1.3%)

problems, reported a higher number of problems in the survey (median 3.0 vs. 2.0; p<.001) and were at greater risk of suboptimal experience (OR 1.4; 95% CI: 1.1-1.9) than cases with only patient-reported problems.

Impact of reported problems in relation to experience dimensions

Patients most frequently reported problems with 'continuity and transition' (52.0%) (Table 3), both among patients with positive and suboptimal experiences. Problems with 'physical comfort' were least common (8.9%) (Table 3). For each patient experience dimension, patients reporting problems were at increased odds of a suboptimal experience, with adjusted odds ratios ranging from 2.4 ('continuity and transition') to 4.4 ('physical comfort) (Table 3). Complication and/or incident occurrence only increased the odds of a suboptimal experience when combined with either patient-reported problems about 'continuity and transition' (OR 1.9; 95% CI: 1.1-3.2) or 'respect for patient preferences' (OR 2.2; 95% CI: 1.3-3.7), but not for any of the other dimensions. Patients who reported problems and experienced complications and/or incidents more commonly reported problems on each dimension than patients who reported problems but had no complications/incidents, except for the dimensions 'involvement of family' (35.5% vs 31.7%; p=.219) and 'physical comfort' (10.7% vs. 14.3%; p=.091).

DISCUSSION

This study examined how complications, incidents and patient-reported problems were associated with overall patient experience on a patient level, to reveal ways to improve surgical care. Many patients who reported problems in the survey had no complications/incidents, which

confirms that patient feedback serves as a complementary source of information on quality and safety.[24–27] The study findings increase insight into how complications and incidents may affect patient experience. Complications/incidents only increased risk of suboptimal experience, when patients reported problems with 'continuity and transition' (e.g. danger signals) or 'respect for patient preferences' (e.g. being treated with respect), but not for any of the other dimensions, suggesting that these dimensions are of particular importance for patients with complications and/or incidents. Patients with only complications/incidents but without patient-reported problems were even at lower risk of suboptimal experience than patients without any problems, potentially suggesting adequate responses from staff to ensure positive experiences despite occurrence of complications and/or incidents.

Impact of complications/incidents

Complication/incident occurrence was only associated with presence of patient-reported problems among patients with a suboptimal experience overall, and not among patients with positive experiences. This may suggest that in the suboptimal experience group, complications/incidents had, directly or indirectly, triggered problems related to patient experience dimensions, which may have negatively affected overall experience. In the positive group, these problems may have been absent, prevented or solved by adequate responses from staff. That healthcare professionals are able to successfully respond to complications and/or incidents might also be reflected in the remarkable finding that patients with only complications/incidents were at lower risk of suboptimal experience than patients without any complications/incidents or patient-reported problems. Some of these patients may simply have a 'higher threshold' for (reporting) problems and a suboptimal experience, but this may also reflect that staff on surgical wards successfully responded to the situation (e.g. by providing more information or emotional support). This would align with a previous study demonstrating that staff responses to complications have an important impact on patient experience, with the potential to ensure a positive experience in spite of these adverse events.[28] Staff responses may also explain why patients with complications and/or incidents were not more likely to report problems with 'physical comfort' or 'involvement of family' dimensions, whereas they did more frequently report problems on all other dimensions. This reflects the clinical experience that complications or incidents can trigger increased attention to pain management (i.e. physicial comfort dimension) as well as additional conversations with the patient's family.

Impact of patient-reported problems

Patient-reported problems in the survey increased the risk of a suboptimal experience, and this applied to all experience dimensions. Complication and/or incident occurrence only increased risk of suboptimal experiences when combined with patient-reported problems on 'respect for patient preferences' or 'continuity and transition' dimensions. Although the study design does not allow inference on the sequence of these problems (e.g. complication first,

problems with respect second), we know that 'continuity and transition' concerns information provided at discharge, and that most complications/incidents occurred during hospitalisation.[29] Therefore, this finding might reflect that a suboptimal discharge process has more impact on patient experience when patients also have complications/incidents, for example because they notice that they were not adequately informed on how to monitor or care for these complications at home after discharge. That complications/incidents increased the risk of suboptimal experience when problems with 'respect for patient preferences' were also present could indicate that patients are less 'forgiving' of complications/incidents when they also experience problems with this dimension. These findings call for increased attention to the process of discharge information and respect for patient preferences in cases with complications/incidents, and adds to previous studies demonstrating that good communication and being treated with respect and dignity are most important for patient experience in general.[30,31]

Strengths and limitations

Specific strengths of this study include that it used patient-level data on complications, incidents and patient experience, with detailed information on patient experience dimensions. Patient-level analyses of these data are more informative for improvement than hospital-level analyses, because it allows studying whether certain patient experiences, such as suboptimal experiences overall or with a specific dimension, and suboptimal outcomes, such as complications and incidents, actually occur in the same inpatient cases. However, the single centre design is a significant study limitation that may limit generalisability of our findings to other centers or countries. Although the content of patient feedback may differ in other settings, the impact of certain problems in context of each other may be more similar, which needs to be tested in future studies. Underreporting could have affected complication/incident rates, but underreporting will likely be similar in cases with and without patient-reported problems or suboptimal experience and therefore not affect our main findings. Moreover, the data used in this study will likely have an accuracy that is equal to studies dependent record review[32] or billing data.[5] That respondents returned the survey on average 15 days after discharge will have limited recall bias, but the response rate of this routine survey still shows room for improvement even though it is higher than generally observed for patient surveys,[10] and similar to the response rate of the Adult Inpatient Survey.[33] Moreover, respondents did not differ from non-respondents on complication/incident occurrence, which was the outcome of interest. Another limitation of this study is that (fulfilment of) patients' expectations, an important and separate predictor of overall satisfaction,[31,34] could not be taken into account.

Practical implications

While complications and incidents are often the focus of learning, for example, at morbidity and mortality conferences, this study reveals how such an approach would leave most (78%) patients with suboptimal experiences undiscussed. The positive message this study

offers is that patients' experiences are not necessarily negatively affected by complications or incidents ('not all is lost'), and that efforts to respond to the patient's needs does seem to matter. However, it seems that a patient's needs may change in context of complications and/or incidents, in which case some aspects are of particular importance, such as feeling treated with respect and adequately informed for the transition home. The findings of this study call for increased attention to the 'respect for patient preferences' and 'continuity and transition' dimensions of patient experience, particularly in cases with complications and incidents. It is necessary to seek ways to strengthen patient involvement and tailor discharge instructions in these cases. While this was a single centre study, patient-reported problems with information at discharge seem more universal: an international comparison of patient surveys showed that 'danger signals' (i.e. item 15) was the item with the highest percentage of patients reporting a problem in the UK (59.9% of 3529 respondents), and second-highest in Switzerland, Sweden and Germany.[13]

Future directions

Relations between complications, incidents and patient experience are complex and thus require in-depth investigations, such as analyses in context of each other. Although these type of studies are complicated by the fact that patient survey data are often anonymous and aggregated at the provider level, patients themselves may be supportive of data linkage for care improvement.[35] Important avenues for further study include how patients' experience and needs may change when complications/incidents emerge and how we should respond adequately–requiring qualitative rather than quantitative study designs. Moreover, studies should explore how patients' expectations may play an additional role. Future studies should also take data on timing of survey response into account when studying the relation between readmission and patient experience, as the present study demonstrated that the relation between readmission and patient experience was affected by timing of survey response (i.e. before or after readmission). Moreover, data on timing could be used to examine the potential for recall bias in surveys by assessing the number of days between discharge and response.

CONCLUSIONS

This study assessed the association between complications and incidents reported by surgical staff and specific problems and overall experiences reported by patients. The study highlighted how patient-level data linkage of patient experience data and staff safety reporting data can reveal ways to improve surgical inpatient care. The findings confirm that patient experiences serve as a complementary source of information on quality and safety, because many patients who reported problems in the survey had no complications/incidents. Other findings reflected the value of staff responses to complications/incidents to meet the patients' needs, such as

regarding physical comfort and family involvement. Although complications/incidents did not independently increase the risk of a suboptimal experience, they did when patients also reported problems on 'patient preferences' or 'continuity and transition' dimensions, suggesting that increased attention is needed for these matters in surgical inpatient care, particularly when complications and/or incidents occur.

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REFERENCES

1. HCAHPS Fact Sheet. June 2015. Centers for Medicare & Medicaid Services (CMS). Baltimore, MD, USA. http://www.hcahpsonline.org/Files/HCAHPS_Fact_Sheet_June_2015.pdf (Accessed 20 October 2017).
2. DeCourcy A, West E, Barron D. The National Adult Inpatient Survey conducted in the English National Health Service from 2002 to 2009: how have the data been used and what do we know as a result? *BMC Health Serv Res*. 2012;12:71.
3. Tsai TC, Orav EJ, Jha AK. Patient satisfaction and quality of surgical care in US hospitals. *Ann Surg*. 2015;261(1):2-8.
4. Sacks GD, Lawson EH, Dawes AJ, et al. Relationship Between Hospital Performance on a Patient Satisfaction Survey and Surgical Quality. *JAMA Surg*. 2015;150(9):858.
5. Kennedy GD, Tevis SE, Kent KC. Is There a Relationship Between Patient Satisfaction and Favorable Outcomes? *Ann Surg*. 2014;260(4):592-600.
6. Tevis SE, Kennedy GD. Patient satisfaction: does surgical volume matter? *J Surg Res*. 2015;196(1):124-129..
7. Isaac T, Zaslavsky AM, Cleary PD, Landon BE. The Relationship between Patients' Perception of Care and Measures of Hospital Quality and Safety. *Health Serv Res*. 2010;45(4):1024-1040.
8. Jha AK, Orav EJ, Zheng J, Epstein AM. Patients' Perception of Hospital Care in the United States. *N Engl J Med*. 2008;359(18):1921-1931.
9. Kemp KA, Santana MJ, Southern DA, McCormack B, Quan H. Association of inpatient hospital experience with patient safety indicators: a cross-sectional, Canadian study. *BMJ Open*. 2016;6:e011242.
10. Lobo Prabhu K, Cleghorn MC, Elnahas A, et al. Is quality important to our patients? The relationship between surgical outcomes and patient satisfaction. *BMJ Qual Saf*. 2018;27(1):48-52.
11. Hofstede SN, Van Bodegom-Vos L, Kringos DS, Steyerberg E, Marang-van de Mheen PJ. Mortality, readmission and length of stay have different relationships using hospital-level versus patient-level data: an example of the ecological fallacy affecting hospital performance indicators. *BMJ Qual Saf*. 2018;27(6):474-483.
12. Marang-van de Mheen PJ, Nallamothu BK. Exclusions in the denominators of process-based quality measures: the missing link in understanding performance or ecological fallacy? *BMJ Qual Saf*. 2017;26(3):169-173.
13. Jenkinson C, Coulter A, Bruster S. The picker patient experience questionnaire: Development and validation using data from in-patient surveys in five countries. *Int J Qual Heal Care*. 2002;14(5):353-358.
14. Boosman H, de Vos M, Kievit J, Marang-van de Mheen P. Patiëntervaringen: meten én verbeteren met een basisset gevalideerde vragen [Article in Dutch]. *KiZ*. 2016;5:22-25.
15. Lawton R, O'Hara JK, Sheard L, et al. Can staff and patient perspectives on hospital safety predict harm-free care? An analysis of staff and patient survey data and routinely collected outcomes. *BMJ Qual Saf*. 2015;24(6).
16. Coulter A, Locock L, Ziebland S, Calabrese J. Collecting data on patient experience is not enough: they must be used to improve care. *BMJ*. 2014;348:g2225.
17. Kievit J, Krukerink M, Marang-van de Mheen PJ. Surgical adverse outcome reporting as part of routine clinical care. *Qual Saf Health Care*. 2010;19(6):e20.
18. de Vos MS, Hamming JF, Marang-van de Mheen PJ. Learning From Morbidity and Mortality Conferences: Focus and Sustainability of Lessons for Patient Care. *J Patient Saf*. 2017 Oct 30 [Epub ahead of print]. doi:10.1097/PTS.0000000000000440.

19. *World Alliance for Patient Safety. WHO Draft Guidelines for Adverse Event Reporting and Learning Systems*. Geneva: World Health Organization; 2005.
20. Rowin EJ, Lucier D, Pauker SG, Kumar S, Chen J, Salem DN. Does Error and Adverse Event Reporting by Physicians and Nurses Differ? *Jt Comm J Qual Patient Saf*. 2008;34(9):537-545.
21. Christiaans-Dingelhoff I, Smits M, Zwaan L, Lubberding S, Van Der Wal G, Wagner C. To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports? *BMC Health Serv Res*. 2011;11:49.
22. Krol MW, de Boer D, Delnoij DM, Rademakers JJDJM. The Net Promoter Score - an asset to patient experience surveys? *Heal Expect*. 2015;18(6):3099-3109.
23. Graham C, McCormick S. *Overarching Questions for Patient Surveys: Development Report for the Care Quality Commission (CQC)* . Oxford; 2012.
24. O'Hara JK, Armitage G, Reynolds C, et al. How might health services capture patient-reported safety concerns in a hospital setting? An exploratory pilot study of three mechanisms. *BMJ Qual Saf*. 2017;26:42-53.
25. Weingart SN, Pagovich O, Sands DZ, et al. What can hospitalized patients tell us about adverse events? Learning from patient-reported incidents. *J Gen Intern Med*. 2005;20(9):830-836.
26. Weissman JS, Schneider EC, Weingart SN, et al. Comparing Patient-Reported Hospital Adverse Events with Medical Record Review: Do Patients Know Something That Hospitals Do Not? *Ann Intern Med*. 2008;149(2):100.
27. Ward JK, Armitage G. Can patients report patient safety incidents in a hospital setting? A systematic review. *BMJ Qual Saf*. 2012;21(8):685-699.
28. Weissman JS, López L, Schneider EC, Epstein AM, Lipsitz S, Weingart SN. The association of hospital quality ratings with adverse events. *Int J Qual Heal Care*. 2014;26(2):129-135.
29. Marang-van De Mheen PJ, Van Duijn-Bakker N, Kievit J. Adverse outcomes after discharge: Occurrence, treatment and determinants. *Qual Saf Heal Care*. 2008;17:47-52.
30. Doyle C, Reed J, Woodcock T, Bell D. Understanding what matters to patients – identifying key patients' perceptions of quality. 2010;1(3):1-6.
31. Bowling A, Rowe G, Lambert N, et al. The measurement of patients' expectations for health care: A review and psychometric testing of a measure of patients' expectations. *Health Technol Assess* 2012; 16(30).
32. Marang-van de Mheen P, van Hanegem N, Kievit J. Effectiveness of routine reporting to identify minor and serious adverse outcomes in surgical patients. *Qual Saf Health Care*. 2005;14(5):378-382. doi:10.1136/qshc.2004.013250.
33. CQC. Adult inpatient survey 2016 (Published July, 2017). http://www.cqc.org.uk/publications/surveys/adult-inpatient-survey-2016 (Accessed 21 May 2018).
34. Bjertnaes OA, Sjetne IS, Iversen HH. Overall patient satisfaction with hospitals: Effects of patient-reported experiences and fulfilment of expectations. *BMJ Qual Saf*. 2012;21:39-46.
35. Flott KM, Graham C, Darzi A, Mayer E. Can we use patient-reported feedback to drive change? The challenges of using patient-reported feedback and how they might be addressed. *BMJ Qual Saf*. 2017;26:502-507.

Chapter 8

Text paging of surgery residents: Efficacy, work intensity, and quality improvement

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ABSTRACT

Background

Text pages can communicate important information but also disrupt workflow, which can affect the safety of patient care. The purpose of this study was to analyze the content, volume, and distribution of text pages received by general surgery residents and physician's assistants (PAs) using natural language processing (NLP).

Methods

We studied text pages received by residents and PA's at a tertiary care teaching hospital from March to May 2012 using NLP. Paging volume and content were stratified by recipient seniority, surgical service, patient census, and patient location. Chi-square tests, t-tests, and analysis of variance were used to detect statistical significance.

Results

We captured 48,202 pages. The average number (mean ± standard deviation) of pages per hour was 3.1 ± 2.2 for postgraduate year (PGY)-1s and 2.8 ± 1.9 for PAs (P <.0001). The greatest number of pages per day by service was 86.1 ± 37.5 on acute care surgery service. The most common paging topic was medications (18,444 [38.3%]) and the most common symptom was pain (6,240 pages [12.9%]). On services where patients were located near each other (regionalized), the number of pages per day per recipient per patient on census was almost half that compared with nonregionalized services (1.40 vs 2.43; P<.0001).

Conclusions

Residents receive a high volume of pages at this tertiary care center, particularly regarding medications and pain. Services with regionalized patients exhibit less paging need per patient. Initiatives to improve pain management and regionalize patients may streamline communication, decrease the number of pages, and increase patient safety.

Key words: Natural Language Processing, text paging, paging, resident paging, surgical residents

INTRODUCTION

Communication between health professionals is critical to patient safety and work efficiency, so it is important that electronic communication protocols such as paging are effective. Although many different systems of medical communication and information technology have been implemented, studied and improved, there is limited evidence that our communication has actually improved.[1] Indeed, it is difficult to measure improvement when the baseline for paging behavior to surgical residents is unclear in terms of both number and content.

At the end of the 1970s, many hospitals still relied on either the physical presence of their house staff on the floor for communication or on complicated "over-head" paging systems.[2] Since then, communication systems have been enhanced, transitioning from overhead paging to numeric paging to alphanumeric "text" paging. The evolution of text paging was considered a boon to residents, because this enabled them to triage their pages.[3,4] Nonetheless, frequent paging of residents and physician's assistants (PAs) interrupts workflow and patient care.[2,5-8] A text page can call a clinician's attention to an opportunity to prevent harm, but can also distract the clinician from a task at hand, potentially leading to harm.

Multiple prior studies estimated paging volume at 1-5 pages per hour.[2,9] Although this number of pages may not sound disruptive, one must consider that residents and PAs are quite busy even when they receive no pages per hour. The baseline tasks of both residents and PAs vary by level but all residents and PAs are responsible for performing surgery in the operating room, postoperative checks, assessment of patients in person as their postoperative status evolves, order entry after rounding, review and response to all lab and radiology tests ordered on each patient, minor procedures in patient rooms, admission of patients from clinic or as a transfer from another hospital, consenting patients for procedures, and communicating with the patients and their families. Meanwhile, responding to pages usually requires an order entry or a return phone call as the nurses don't carry pagers. Because of the effort required to respond to a page, receipt of a single page can take significant time. These interruptions, distractions and changes in focus away from these baseline tasks have been reported to be an important cause of active errors.[10] Human error is one of the greatest contributors to accidents in health care and patient safety.[11] By assessing the communication method of paging, we may find an opportunity to make systems changes that improve patient safety and the quality of care we provide while also decreasing the number of pages.[12]

Prior studies have suggested that a decrease in the number of pages can occur through improved communication, reduction of redundant paging, and postponement of nonurgent pages.[2] To assess the urgency and possible redundancy of pages, it is important to not only understand the number and timing of pages, but also the content of pages. Although the number of pages has been investigated, there are no prior studies detailing the content of these text pages or correlating the quantitative and qualitative aspects of text pages that can explain how they help and hurt a clinician's ability to care for patients. Using the technique of natural

language processing (NLP), our aim was to quantify paging topics to identify opportunities to improve on efficiency of text paging and to decrease the number of pages while improving patient care and maintaining a high quality of communication between providers.

METHODS

We obtained 48,202 time-stamped text pages received by 31 general surgery residents in post-graduate years (PGY) 1-3 and 3 PAs at a tertiary care hospital from March through May 2012. In this hospital, the PAs assist with preoperative and postoperative surgical care for patients on the floor. They function similarly to interns except that they work 4 days per week for 10 hours each day and are less likely to go to the operating room (OR). Our study did not exclude any page senders. Pages were limited to 200 characters of alphanumeric text.

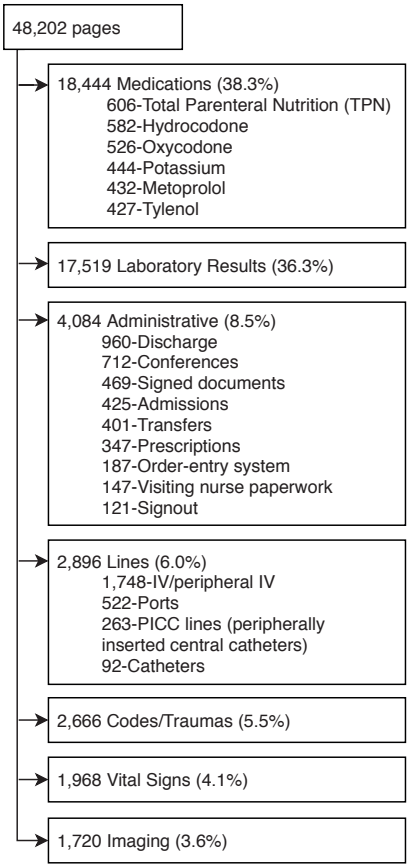
The paging data was anonymized using a Python Programming Language (available from: *www.python.com*; Worldwide Distributed Development) script so that names of all senders, recipients, and patients were replaced with a random identifier. An NLP program was written in Python to identify words of interest from a list of Medical Subject Headings (MeSH terms) referred to as the MeSH term dictionary.[13] Common abbreviations for terms such as "abdomen" were added manually to the dictionary so that "abd" in a text page would be identified as the MeSH term "abdomen." Paging content was then analyzed using the linguistic-based NLP program.[14] The output of the program included a list of MeSH terms and the number of times each term occurred in the paging data. Misspellings were corrected manually. MeSH terms were then categorized manually by topic (medications, laboratory results, etc), system, and symptom (Figure 1, Table 1). These topics were not mutually exclusive. For example, the MeSH term "metoprolol" was categorized under both "medication" and "cardiac."

We used the Tableau Visual Analytics Tool (Tableau Software, Seattle, WA) to assess the results graphically and analyze trends in paging over time by recipient, surgical service, and paging context. Number of pages and content were assessed by controlling for PGY level (or PA), patient census of service, and whether patient beds on the service were close to each other (regionalized) on the same hallway or floor.

Using work schedules, we identified the number of residents and PAs on service at any given time. We calculated number of pages per day by service and by recipient. We also adjusted for the patient census by service to create the unit of pages per day per recipient per patient census (pages/day/recipient/pt census). Page to some residents were unavailable for analysis because they had left the institution; this loss of pages decreased the number of pages available for analysis on some services but there was ≥1 month's worth of pages available for every service.

To study paging behavior by surgical service location, we compared regionalized services (where patients were located on the same floor or hallway) to nonregionalized services (where patients were located on different floors and in different parts of the hospital). For nonregion-

Figure 1. Flow chart. Text pages may include content from multiple categories.



alized services we used 2 general surgery services and focused only on the patients on their regular patient wards as opposed to those in the intensive care unit (ICU). For regionalized services we used both ICU services as well as ward services. Most of our ICUs consist of 1 circular arrangement of 10 patient beds with a desk and computer available for the resident on call. The only exception is the cardiac surgery ICU, which is arranged the same way as vascular surgery; the beds are all on 1 floor and with 28 patient beds in a big circle. The thoracic surgery service consists of 4 pods. Each pod holds 10 patients. One pod is on floor 12 while the remaining 3 pods are on floor 11.

Statistical analysis

We used *t* tests for comparison between means of 2 groups and analysis of variance was used for comparison between the means of multiple groups. All statistical analyses were performed using Statistical Analysis System (SAS) 9.3 software (SAS Institute Inc, Cary, NC). Continuous variables are presented as mean values ± standard deviation.

Table 1. Pages adressing medications.

Medication categories	n (%)
Total	18,444
Pain	3,925 (21.2)
Opioids	2,594 (14.1)
Hydromorphone	684 (3.7)
Oxycodone	650 (3.5)
PCA	572 (3.1)
Epidural/PCEA	261 (1.4)
Fentanyl	180 (1.0)
Morphine	126 (0.7)
Acetaminophen	534 (2.9)
Ketorolac	168 (0.9)
Other	750 (4.1)
Electrolytes	1,385 (7.5)
Cardiac	1,110 (6.0)
Pulmonary	966 (5.2)
Antibiotics	913 (5.0)
Insulin	872 (4.7)
Anticoagulants	854 (4.6)
TPN	689 (3.7)
Antiemetics	580 (3.1)

PCA, Patient-controlled anesthesia; *PCEA*, patient-controlled epidural anesthesia.

RESULTS

Number of pages

A total of 48,202 pages were sent to 31 general surgery residents and 3 general surgery PAs on 25 services in a 3-month period. Over all surgical services, the number of pages received per day by a single recipient ranged from 1 to 249 pages, with an average of 2.7 ± 2.0 pages per hour (minimum [min], 1; maximum [max], 20) across all 3 residency levels and PAs. The average number of pages per hour was 3.1 ± 2.2 (min, 1; max, 20) for PGY-1s, 2.8 ± 1.9 (min, 1; max, 16) for PAs, 2.0 ± 1.4 (min, 1; max, 12) for PGY-2s, and 1.8 ± 1.2 (min, 1; max, 12) for PGY-3s (P <.0001). When analyzed by day (6 am-6 pm) and night (6 pm-6 am) rotations, similar results were found (Table 2). The number of pages per hour was greater during the day than at night for every PGY level except for PGY-2s, consistent with the data when stratified by surgical service and number of pages per hour (Figure 2).

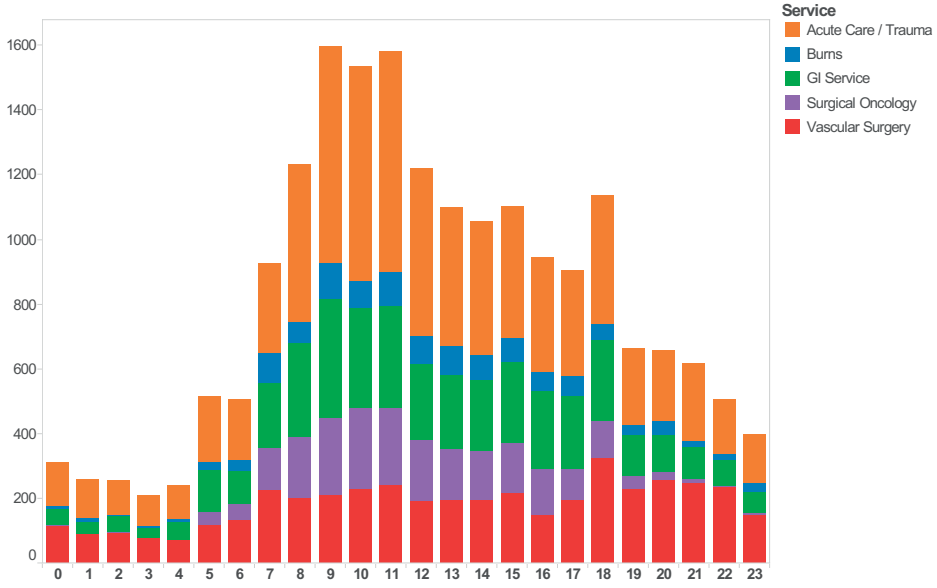
By surgical service, the average number of pages per day ranged widely from 9.5 ± 2.0 (min, 1; max, 30) on the burn / trauma ICU to 86.1 ± 2.0 (min, 3; max, 192) on the acute care surgery service. The number of pages per day was highest for the acute care surgery and thoracic surgery services. When controlled for census, services with the greatest mean number of

Table 2. Pages per hour by recipient role and day versus night rotations.

	PA	*PGY-1*	*PGY-2*	*PGY-3*
Day: 6 am-6 pm				
Average number pages/h	2.9	3.2	1.8	1.9
Minimum	1	1	1	1
Maximum	16	20	10	12
Standard deviation	2.0	2.3	1.1	1.2
P	.0007	reference	<.0001	<.0001
Night float: 6 pm-6 am				
Average number pages/h	1.4	2.9	2.2	1.6
Minimum	1	1	1	1
Maximum	7	20	12	7
Standard deviation	0.9	2.0	1.6	1.1
P	<.0001	reference	<.0001	<.0001
Overall: 6 am-6 am				
Average number pages/h	2.8	3.1	2.0	1.8
Minimum	1	1	1	1
Maximum	16	20	12	12
Standard deviation	1.9	2.2	1.4	1.2
P	<.0001	reference	<.0001	<.0001

PCA, Patient-controlled anesthesia; *PCEA*, patient-controlled epidural anesthesia.

Figure 2. Mean number of pages over 24 hours (midnight to midnight) by surgical service.



pages / day / recipient / pt census were transplant surgery (5.8) and urology (3.1; Table 3). Residents and PAs on regionalized services experienced fewer mean pages / day / recipient / pt census compared with residents and PAs on nonregionalized services (1.4 ± 0.3 vs 2.6 ± 0.6; P<.0001; Table 4).

Table 3. Number of pages according to surgical service per 24-hour period

Service	*Number of pages per day mean ± SD (min,max)*	*Mean number of recipients*	*Mean pages per day per recipient*	*Mean census of service*	*Mean pages per day per recipient per patient census*
All days (Monday-Sunday)					
Acute care surgery	86.1 ± 37.5 (3, 192)	2.4	35.9	12.8	2.9
Thoracic surgery	61.8 ± 29.3 (1, 120)	1.9	32.5	34.8	0.9
Gastrointestinal surgery	59.3 ± 33.9 (2, 121)	2.2	27.0	29.5	0.9
Surgical oncology	53.7 ± 24.1 (16, 107)	1.3	41.3	21.9	1.9
Vascular surgery	49.1 ± 22.5 (1, 130)	2.0	24.6	14.7	1.7
Neurosurgery	45.0 ± 24.0 (1, 112)	1.3	34.6	19.3	1.7
Cardiac surgery ICU	31.9 ± 20.5 (3, 95)	1.8	17.7	12.3	1.4
Urology	26.4 ± 14.7 (1, 58)	1.0	26.4	8.4	3.1
Burn surgery	13.9 ± 10.2 (1, 46)	1.0	13.9	11.2	1.2
Plastic surgery	13.3 ± 10.6 (1, 42)	1.0	13.3	7.5	1.8
Surgical ICU, general	11.7 ± 10.4 (1, 50)	1.4	8.4	6.6	1.3
Transplant surgery	11.6 ± 7.1 (1, 29)	1.0	11.6	2.0	5.8
Thoracic ICU	11.0 ± 8.6 (1, 36)	1.0	11.0	7.9	1.4
Surgical ICU, burn / trauma	9.5 ± 7.5 (1, 30)	1.0	9.5	6.3	1.5
Weekdays (excluding Saturday and Sunday)					
Acute care surgery	97.5 ± 32.2 (16, 192)	2.7	36.1	13.1	2.8
Thoracic surgery	73.4 ± 24.3 (28, 120)	2.0	26.7	36.2	1.0
Gastrointestinal surgery	65.0 ± 32.9 (5, 121)	204	27.1	31.5	0.9
Surgical oncology	53.9 ± 23.6 (16, 107)	1.3	41.5	22.1	1.9
Vascular surgery	55.0 ± 21.0 (15, 130)	2.1	26.2	15.2	1.7
Neurosurgery	53.0 ± 19.2 (1, 112)	1.4	37.9	21.3	1.8
Cardiac surgery ICU	32.9 ± 20.9 (3, 95)	1.9	17.3	13.2	1.3
Urology	28.8 ± 15.1 (1, 58)	1.0	28.8	9.2	3.1
Plastic surgery	13.3 ± 11.4 (1, 42)	1.0	13.3	8.0	1.7
Transplant surgery	12.3 ± 7.5 (1, 29)	1.0	12.1	1.9	6.5
Burn surgery	12.1 ± 7.6 (1, 29)	1.0	12.3	10.9	1.1
Surgical ICU, general	12.0 ± 10.8 (1, 50)	1.4	8.6	6.7	1.3
Thoracic ICU	11.5 ± 9.2 (1, 36)	1.0	11.5	7.9	1.5
Surgical ICU, burn / trauma	9.7 ± 7.5 (1, 30)	1.0	9.7	6.2	1.6

ICU, Intensive care unit; *SD,* standard deviation.

Table 4. Number of pages per day per recipient per patient census

	Nonregionalized services (mean = 2.6)		*Regionalized services (mean = 1.4*)*					
Month	*Trauma / acute care surgery (census)*	*Oncologic surgery (census)*	*Surgical ICU, burn/ trauma (census)*	*Surgical ICU, general (census)*	*Thoracic surgery ICU (census)*	*Cardiac surgery ICU (census)*	*Vascular surgery (census)*	*Thoracic surgery (census)*
March	3.2 ± 1.2 (11.5)	1.8 ± 0.8 (19.4)	2.1 ± 1.6 (4.6)	1.0 ± 0.6 (6.5)	1.6 ± 1.2 (9.3)	1.8 ± 0.9 (11.0)	1.7 ± 0.7 (16.0)	0.9 ± 0.3 (35.1)
April	2.6 ± 1.1 (14.2)	1.9 ± 0.7 (25.4)	1.1 ± 0.9 (6.5)	1.7 ± 1.1 (6.1)	1.2 ± 0.7 (7.1)	1.3 ± 0.6 (13.3)	1.9 ± 0.6 (13.4)	0.9 ± 0.3 (38.4)
May	3.2 ± 1.5 (12.8)	2.8 ± 0.9 (21.6)	1.5 ± 1.2 (7.5)	1.1 ± 0.9 (7.3)	1.6 ± 1.4 (7.9)	1.4 ± 0.7 (12.6)	1.4 ± 0.6 (14.7)	1.0 ± 0.3 (31.3)

ICU, Intensive care unit; *SD,* standard deviation.

Content of pages

Of all 48,202 pages, 38.3% were about medications, 36.3% were about laboratory results, and 8.5% were about administrative concerns (Figure 1). Given that these topics (medications, laboratory results, administrative, etc) are pertinent to all organ systems (cardiac, pulmonary, urinary) and symptoms (pain, diet, nausea and vomiting), pages were also tagged by system and symptom. Overall, the most common symptom was pain (6,240 pages, 12.9% of all pages) and the most common system was cardiac (2,782 pages, 5.8%). Of all pages about medications (18,828), the most common classes of medications involving pages addressed pain (3,925 pages, 20.8%), electrolytes (including potassium, magnesium, calcium, and phosphate repletion; 1,385 pages, 7.4%), cardiac medications (1,110 pages, 5.9%), and pulmonary medications (966 pages, 5.1%; Table 1). The most frequently discussed pain medications were opioids (2,594 pages, 66.1%), the most commonly mentioned opioids were hydromorphone (684 pages, 17.4%), oxycodone (650 pages, 16.6%), and patient-controlled anesthesia (572 pages, 14.6%). Of all medications addressed via paging, the most frequently mentioned were total parenteral nutrition (689 pages, 3.7%), hydromorphone (684 pages, 3.6 %), and oxycodone (650 pages, 3.5%) (Table 1).

DISCUSSION

The number of pages received by interns, residents, and PAs was consistent with their duties and type of service. Number of pages averaged 3.1 per hour for interns, which is consistent with prior published studies showing 1-5 pages per hour. Our study also identified the impact of recipient training level and time of day on paging volume and includes data about peak paging volume. PAs have a similar paging volume to interns (2.8 per hour), which is expected,

because PAs do a similar job caring for surgical patients on the patient care floor in our institution. The number of pages may be slightly lower as they spend less time in the operating room (OR) and so have more time available to be directly present with patients and other care providers on the floors. PAs also have more clinical experience than the interns and have had time to build trust with other care providers. These and other factors may explain the slightly fewer number of pages per PA compared with the interns.

We found lesser overall rate of paging for PGY-2 and PGY-3 residents compared with interns. At our tertiary care hospital, the PGY-2 residents spend about one-half of their year managing patients in the ICU's. These units are limited to 10 patients who are all located in 1 circular hallway, which makes communication between the providers (doctors, nurses, respiratory therapists, and pharmacists) much easier, because everyone can easily meet face to face. The physical layout of these units may explain the decreased number of pages to the PGY-2 residents, especially because ICUs are regionalized services, and these units used fewer text pages compared with nonregionalized services. In our hospital, the PGY-3 residents are often responsible for the surgical consults, which may explain why their number of pages includes the initial consult page as well as any follow-up pages regarding questions or clarifications in patient management. Because the primary teams are responsible for enacting the recommendations of consultants, the PGY-3 residents generally do not receive pages regarding ward management for patients in whom they are asked to provide a consultation. This may explain the lesser number of pages sent to PGY-3 residents. We believe that the decrease in the number of pages from PGY-1 to PGY-3 reflects their decreased direct responsibilities to floor and ICU patients as well as their increased responsibilities in the operating room.

Although the number of pages may average 1.8-3.1 pages/hour, recipients received as many as 20 pages per hour. The effect of such a communication load on residents, PAs, and patient safety is unknown and worthy of further study. While much effort has been focused on decreasing human error by limiting resident work hours, the level of work intensity may also play a role in human error and patient safety.

A wide range in number of pages per hour was noted for all groups of paging recipients. Although the range is greater (≤20 pages per hour) for PGY-1 residents than for senior residents (≤12 pages per hour), these data illustrate the unpredictable nature of each day for residents and PAs. It is difficult to plan for many social or family occasions, because the resident may not know if it will be a 16-page day or a 192-page day. In an era where all healthcare providers are increasingly evaluated on their communication skills and their standardized test scores, there is no formal truly protected time for communication with patients and family or for studying a disease process.

Pain was overwhelmingly the most popular symptom discussed by paging, which may suggest that surgeons were systematically undertreating pain in the study period. Before to the time period of this study, our hospital had implemented protocols for management of pain medications and created a postoperative pain service to assist the surgical services. Nurses

across all services are allowed limited options for dose adjustment of pain medications, but these include a few small bolus doses for breakthrough pain when a patient has a patient-controlled anesthesia device or administration of a narrow range of oral pain medications (examples such as 5-10 milligrams of oxycodone or 1-2 milligrams of hydromorphone). Despite these measures, there remains the need for paging as a form of communication regarding patient pain compared to other medical issues. Based on the results of this study, we held a meeting that included the heads of surgical nursing, the chief medical officer of the hospital (the senior author of this study [S.W.A.]), and a representative of surgical residents (the first author [A.D.B.S.]). Pain management was discussed and the point of transition from intravenous pain medication to oral pain medication was identified as a potential source for the greatest number of pages about pain. For this reason, a next step for this study includes creation of a protocol specifically for transition from intravenous to oral pain medication in our hospital.

Finally, our study identified clear differences in paging behavior between regionalized and nonregionalized surgical services. Services with patients whose beds were in close proximity to each other (regionalized) sent fewer pages per patient than did those services whose patients were spread out across the hospital (nonregionalized). This difference may be a result of several factors. Services with regionalized patients are staffed by nurses who regularly care for the same type of patient, likely resulting in a greater level of comfort with patient care. Additionally, when a clinician comes to the ward to see a patient, they can easily see other patients on that service and address issues in person without requiring pages to be sent. Not only are the patients regionalized, but the nurses caring for all of their patients are also grouped together. This proximity facilitates in-person communication, builds trust between clinicians, and makes it easier to address patient concerns. Comparisons of organized inpatient care by specialty versus care on general wards have been found in prior studies to improve patient outcomes such as reduction in the odds of death.[15] In contrast, when patients are dispersed, the nursing staff may be less familiar with the care protocols of any given service and less familiar with the residents and PAs caring for the patient. This situation creates an environment where familiarity and time to spend with the patients and nursing staff is less, requiring increased levels of communication via paging. Given this finding, we plan to try to better implement the regionalization of all general surgery patients in our tertiary care hospital to increase the quality and safety of patient care.

Although an educational intervention regarding paging could be beneficial to both page senders and recipients, measuring the impact of such an intervention would be difficult owing to ongoing regionalization of surgical services and new additional pain management protocols. We plan to assess a new baseline for paging once these changes have occurred and then consider an educational intervention.

This study is limited by being a single-institution study at an academic medical center and therefore may not be generalizable to other hospitals. Another limitation is that there were

some residents (9 interns and 2 PGY-3 residents) who had already left our tertiary care hospital by the time the pages were retrieved; therefore, the pages they had received were already deleted from storage. For this reason, the rotations they covered from March-May 2012 do not show any pages. These absent values did not contribute to any surgical service totals or averages, but their absence reduced the number of months of data we had for some services. As a result, our paging volume by service may vary in future studies.

Furthermore, to meet the requirements of resident duty hours by giving the on-service resident 1 day off each week, another resident or moonlighter covered the service. Because we did not have the coverage schedule for residents, we were unable to capture service-related pages on these days. Also, because our data periodically shows about 1-3 pages per day for the usually busy service on some days, it seems likely that these were the days when the resident who covered the service could not be identified. For this reason, paging volumes by service may further be underestimated.

Our measure of the number of pages per day per resident in Table 3 is not weighted for working during the day versus the night, which should be considered when comparing paging volume between services. As shown in Figure 2, there are a greater number of pages across services from 6 am to 6 pm when the day residents residents and PAs work compared with 6 pm to 6 am when the night resident is on call. The same difference in number of pages is quantified in Table 2 where pages per hour were compared between the day recipients and the night float recipients. For this reason, the measures underestimate the number of pages residents and PAs received during the day and overestimate the number of pages received by the resident at night, because the total number of pages per day is divided by the total number of residents and PAs who received pages for the service in any 24-hour period.

No call schedules were accounted for in this analysis, because our services work on a night float system rather than an on-call system. One or more residents and PAs cover a service during the day from 6 am to 6 pm. A different resident covers the service at night from 6 pm to 6 am. Schedules vary on the weekends. For this reason, the results in Table 3 that show the mean number of pages per day to the surgical services were split to exclude any data from weekends; however, show the same effect is shown.

These limitations notwithstanding, our study represents a detailed analysis of quantity and content of pages during the conduct of care for surgical services within a tertiary teaching hospital. Our results are likely an underestimation of the number of pages that occur, and hence further support the need for changes that improve work efficiency and hospital communication while maintaining excellent patient care.

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REFERENCES

1. Wu RC, Tran K, Lo V, O'Leary KJ, Morra D, Quan SD, et al. Effects of clinical communication interventions in hospitals: A systematic review of information and communication technology adoptions for improved communication between clinicians. *Int J Med Inform*. 2012;81(11):723- 732.
2. Katz MH, Schroeder SA. The sounds of the hospital. Paging patterns in three teaching hospitals. *N Engl J Med*. 1988;319(24):1585-1589.
3. Nguyen TC, Battat A, Longhurst C, Peng PD, Curet MJ. Alphanumeric paging in an academic hospital setting. *Am J Surg*. 2006;191(4):561-565.
4. Wong BM, Quan S, Shadowitz S, Etchells E. Implementation and evaluation of an alphanumeric paging system on a resident inpatient teaching service. *J Hosp Med*. 2009;4(8):E34-40.
5. Blum NJ, Lieu TA. Interrupted care. The effects of paging on pediatric resident activities. *Am J Dis Child*. 1992;146(7):806-808.
6. Espino S, Cox D, Kaplan B. Alphanumeric paging: A potential source of problems in patient care and communication. *J Surg Educ*. 2011;68(6):447-451.
7. Coiera E, Tombs V. Communication behaviours in a hospital setting: An observational study. *BMJ*. 1998;316(7132):673-676.
8. Volpp KG, Grande D. Residents' suggestions for reducing errors in teaching hospitals. *N Engl J Med*. 2003;348(9):851-855.
9. Patel SP, Lee JS, Ranney DN, Al-Holou SN, Frost CM, Harris ME, et al. Resident workload, pager communications, and quality of care. World J Surg. 2010;34(11):2524-9.
10. Reason J. *Human error.* New York: Cambridge University Press; 1990.
11. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. Washington (DC): National Academies Press; 2000.
12. Kohn LTJ, Corrigan JM. Institute of medicine (IOM) report - to err is human: Building a safer health system. 1999.
13. U.S. National Library of Medicine. National Institutes of Health. (14 July 2013). Retrieved August 12, 2013 from http://www.nlm.nih.gov/mesh/filelist.html
14. Friedman C, Rindflesch TC, Corn M. Natural language processing: State of the art and prospects for significant progress, a workshop sponsored by the National Library of Medicine. J Biomed Inform. 2013 Oct; 46(5):765-73.
15. Stroke Unit Trialists' Collaboration, "Organised inpatient (stroke unit) care for stroke," Cochrane Database of Systematic Reviews, no. 9, article CD000197, 2013.

Chapter 9

Preoperative anticoagulation management in everyday clinical practice: an international comparative analysis of work-as-done using the functional resonance analysis method

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ABSTRACT

Objectives

Preoperative anticoagulation management is a complex, multidisciplinary process important to patient safety. The Functional Resonance Analysis Method (FRAM) is a novel method to study how complex processes usually go right at the frontline (labelled Safety-II), and how this relates to predefined procedures. This study aimed to assess preoperative anticoagulation management in everyday practice and explore the usability and utility of FRAM.

Methods

The study was conducted at an Australian and European Cardiothoracic Surgery department. A FRAM model of work-as-imagined was developed using (inter)national guidelines. Semi-structured interviews with 18 involved professionals were used to develop models reflecting work-as-done at both sites, which were presented to staff for validation. Workload in hours was estimated per process step.

Results

In both centers, work-as-done differed from work-as-imagined, such as in the division of tasks among disciplines (e.g. nurses/registrars rather than medical specialists), but control mechanisms had ben developed locally to ensure safe care (e.g. crosschecking with other clinicians). Centers had organized the process differently, revealing opportunities for improvement regarding patient information and clustering of clinic visits. Presenting FRAM models to staff initiated discussion on improvement of functions in the model that are vital for success. Overall workload was estimated at 47 hours per site.

Conclusions

This FRAM analysis provided insight into preoperative anticoagulation management from the perspective of frontline clinicians, revealing essential functions, interdependencies and variability, and the relation with guidelines. Future studies are warranted to study the potential of FRAM, such as for guiding improvements in complex systems.

Key words: medication safety; patient safety; continuous quality improvement; safety-II; FRAM

INTRODUCTION

Anticoagulation is a common and effective therapy for patients with an increased risk of thromboembolic events (e.g. due to atrial fibrillation or mechanical heart valves)[1,2] yet also responsible for a substantial proportion of medication-related adverse events.[3–6] Management of anticoagulation therapy is delicate and complex, especially around surgical procedures where it involves a trade-off in decision-making: continuation increases the risk of perioperative bleeding, but interruption increases the risk of thromboembolic events (e.g. stroke).[7,8] Some patients may temporarily need 'bridging therapy' (e.g. low-molecular-weight heparin) during interruption of their anticoagulation therapy. A team of healthcare professionals must coordinate anticoagulation care, including medical specialists, nurses, pharmacists, general practitioners, and in some countries, anticoagulation services.[9] Communication and coordination issues are common, increasing risks of adverse outcomes.[9–11] While guidelines have been developed to support this process,[12–16] guideline adherence is highly variable, which may expose patients to unnecessary risks of perioperative complications.[17–20]

Rather than continuing the search for guideline non-adherence and root causes of complications (labelled as the Safety-I approach[21]), a promising alternative is to increase understanding of this complex process in everyday practice, including the capacities that facilitate safe patient care. This approach, referred to as Safety-II, is linked to other positive approaches to patient safety, such as positive deviance,[22,23] appreciative inquiry[24] or learning from excellence.[25] Safety-II seeks to understand how processes usually go right at the front line, and how this relates to predefined procedures, such as protocols or process design.[26–28] Analysis of actual practice is also recognized as an important first step when striving to implement improvements.[29] A useful tool for this purpose is the Functional Resonance Analysis Method (FRAM), which has been endorsed by safety experts, such as James Reason,[30] as a promising way forward to improve safety in complex systems. FRAM has been applied in various settings, including aviation,[31] air traffic management,[32,33] railway traffic,[34] manufacturing,[35] and construction.[36] While healthcare is a classic example of a complex system, the uptake of this new approach has been limited in medical research.[37,38]

This study assessed preoperative anticoagulation management (PAM) using semi-structured interviews with front-line clinicians in an Australian and European hospital. The study aimed: (1) to obtain a deeper understanding of how PAM is conducted in everyday practice (work-as-done) and how this relates to predefined procedures (work-as-imagined); and (2) to examine the applicability of a Safety-II approach using FRAM for medication management research, as a tool to reconcile work-as-imagined and actual work-as-done.

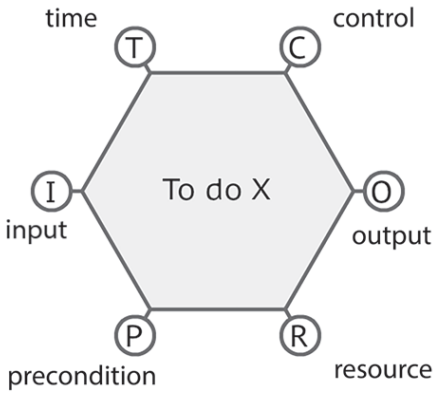
METHODS

This study was conducted at the Cardiothoracic Surgery departments of both an Australian and Dutch university hospital. These settings were selected for high incidence of complex surgeries with patients on anticoagulation therapy regimens. In this study, PAM relates to continuing, ceasing or bridging anticoagulation therapy, including vitamin K-antagonists, non-vitamin K antagonists (e.g. dabigatran, rivaroxaban) and platelet aggregation inhibitors (e.g. acetylsalicylic acid, clopidogrel), in patients planned for elective open-heart surgery.

Functional Resonance Analysis Method

FRAM can be used to describe essential activities that build up a process, visualized in models.[30] In a FRAM model, activities are represented in 'functions' depicted as hexagons with six different labels or 'aspects' (Figure 1). The models can be based on various sources of information, including guidelines, observations or interviews with the frontline. To obtain a deeper understanding of a complex process, FRAM requires a targeted, defined scope.[39] Hence, the focus of this study was limited to the preoperative phase. For detailed information on FRAM, we refer to practical instruction guides[40] and prior publications.[37–39] The study investigators attended workshops on the methodology,[41,42] and were supervised by researchers with experience in Safety-II and FRAM (R.C-W. and J.B.).

Figure 1. FRAM function with all aspects.



In 'To do X', X can represent any activity (e.g. to admit patient). The six aspects represent:
- *input*: what the function starts, acts on, or changes;
- *time*: any time constraints that might affect the function (e.g. by which it will be carried out later);
- *control*: how the function is monitored or controlled, work agreements, visions or objectives;
- *output:* the outcome or state change that emerges from the function;
- *resource*: material or people needed to carry out the function, or consumed *during* the function;
- *precondition*: a condition that must be satisfied *before* the function can be commenced.

Interviews and modeling

In accordance with previous FRAM studies,[37,39] an initial model of PAM 'as-imagined' was constructed based on the leading international guideline from the American College of Chest Physicians[43] and a Dutch national guideline.[44] The Australian Clinical Excellence Commission and Commission on Safety and Quality in Health Care both confirmed that Australia has no common guideline. This initial model provided the basis for semi-structured interviews, which were conducted between April and June 2017 with 18 healthcare professionals involved in PAM (Table 1). Interviewees were purposively selected: the director at the Australian hospital and a senior physician assistant at the Dutch hospital provided the initial point of approach for recruitment, and additional professionals were recruited through interviewees. Interviews were held individually with one interviewer in Australia (N.L.D.) and two interviewers in the Netherlands (M.S.d.V/M.J.M). Following written consent, interviews were audio-recorded and summarized immediately afterwards for the investigators. Interviews were guided by a topic list (Appendix 1) based on questions of the FRAM method, with minor adaptations made for the specific discipline interviewed.[39,40] FRAM models reflecting PAM 'as-done' were developed based on the interviews by the investigators who also conducted the interviews. An iterative modeling process was applied with preliminary models developed after each interview, and updated versions guiding the following interviews. The 'FRAM Model Visualizer' was used to construct FRAM models.[45] Interviews were conducted until data saturation was reached for the model,[46] defined as three consecutive interviews during which no new functions emerged for the model. In both hospitals, a discussion meeting was organized to present the final models to involved staff as a means of validation, and to elaborate on potential clinical implications and recommendations. To examine usability of this novel method (e.g. for quality managers), total workload in hours was estimated per step of the FRAM analysis (excluding study-related work, such as drafting the manuscript).

Analyses

FRAM models can be studied by assessing variability and interdependence of functions.[38,40] Variability can be due to human, organizational or environmental factors affecting timing or precision of functions.[38] Functions may also be interdependent (known as 'coupling') in which case a function impacts later functions ('functional upstream-downstream coupling'). This interdependence between functions may allow variability in one function to spread through the process, e.g. information omitted in one function may impact later functions that use this information. Variability and interdependence was assessed for the 'foreground functions', which are the main steps in the process depicted in hexagons, in contrast to 'background functions' depicted in grey boxes, which are considered to be more stable and have a less prominent role in analysis.

Table 1. FRAM process steps and disciplines interviewed, with estimated workload per site.

Process steps			Time (hours)†
Work-as-imagined model	Development of model based on international guidelines.		7
Interviewed professionals (n)* incl. preparations, processing, and iterative model development	*AUSTRALIA (10):* ● Cardiothoracic surgeon (1) ● Cardiologist (2) ● Nurse case manager (1) ● Nurse unit manager(2) ● Anesthetist (1) ● Pre-admission clinic nurses (3)*	*THE NETHERLANDS (8):* ● Cardiothoracic surgeon (1) ● Cardiologist (1) ● Cardiothoracic PA (2) ● Registrars (2) ● Anesthetist (1) ● Planning office secretary (1)	20
Work-as-done model	Development of final model based on information gathered in interviews and analysis of potential variability and interdependence.		15
Meeting with frontline (team discussion)	Department meeting gathering all involved staff to present, validate and discuss the final model (ca. 1-2 hours), with subsequent processing of feedback.		5
TOTAL			47

PA, physician assistant.

* Interviewed disciplines differ because of the different disciplines involved in the centers (Table 1). Australian interviews were conducted in two instances within a two-month time frame because of time limitations for providers. All were interviewed individually, except for the pre-admission clinic nurses who were interviewed together.

† Overall workload per site for the analysis carried out by three main investigators collaboratively.

RESULTS

The PAM 'as-imagined' model reflected guideline recommendations for task division and communications between healthcare professionals. A key role was assigned to anesthetists, who were expected to decide upon a definitive PAM strategy (i.e. to continue, cease or bridge), after a proposal by treating physicians, and to inform patients and other clinicians (Appendix 2). Interviews with healthcare professionals about PAM 'as-done' lasted between 45 and 60 minutes. Data saturation was reached for the models in both settings (Table 1). Notable differences between the models and time investments are discussed in Tables 1 and 2.

Australian model

The Australian model (Figure 2) consists of 8 main functions:

1. **To decide on surgery and PAM:** at the clinic, cardiothoracic surgeons see referred patients to inform them about the treatment as well as PAM strategy and provide them with a 'pre-admission booklet'.
2. **To discuss PAM with the patient:** subsequently, patients see the nurse case manager (CM) who schedules the surgery, further explains the PAM strategy and checks whether the surgeon noted this on the pre-admission booklet. If not, the nurse asks the surgeon or,

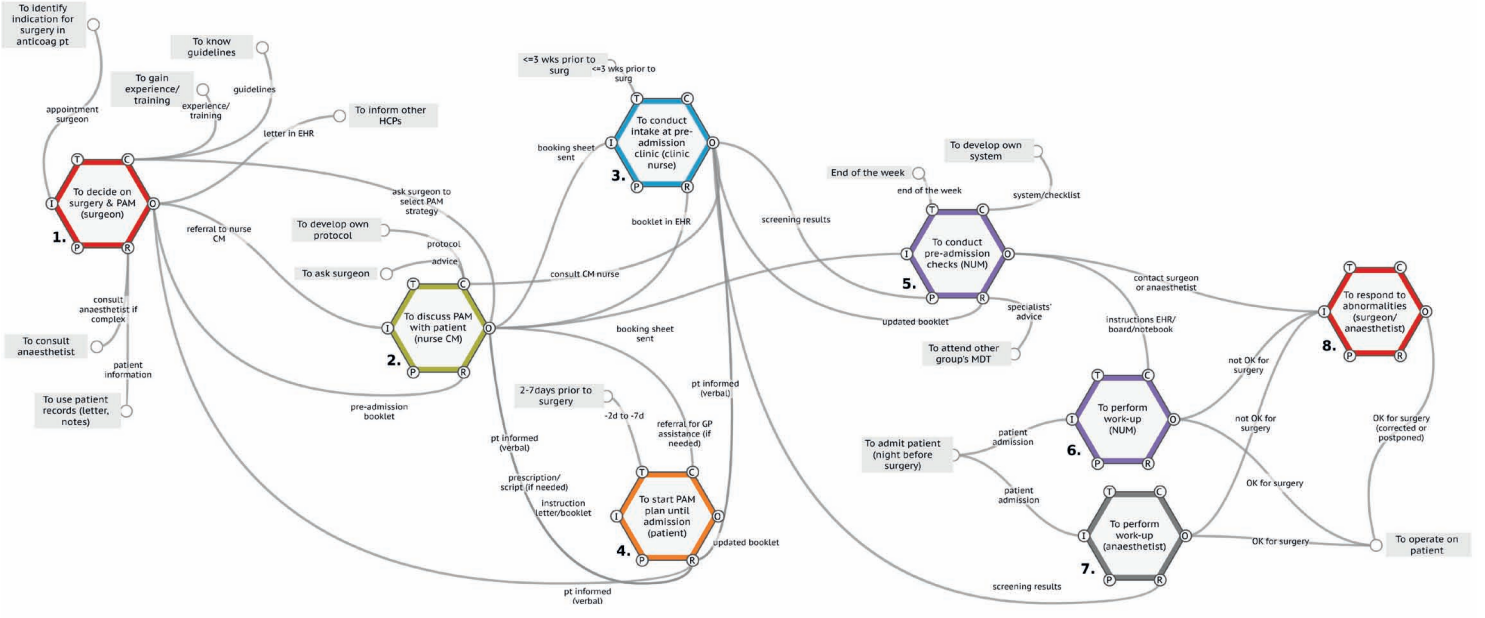
Table 2. Preoperative anticoagulation management 'as-done' in Australia vs. the Netherlands

Theme	Australia	The Netherlands
Patient visits	Two preoperative hospital visits: one with surgeon and afterwards nurse CM, and one pre-admission clinic visit.	One-day preoperative clinic visit, including pharmacy assistant, PA/registrar, cardiothoracic surgeon, and anesthetist.
Disciplines	Central role for nurses, including NUM, nurse CM, and clinic nurse. Anesthetist involved in work-up upon admission and in case of abnormalities.	Central role for PA/registrar and role for planning office secretary. Anesthetist not involved in PAM strategy or in case of abnormalities.
Multidisciplinary communication	NUM might ask questions about PAM strategy during other cardiac group's multidisciplinary meeting.	Daily heart team meeting with surgeon and cardiologist; preoperative clinic with multiple disciplines at same location.
Decision-making	Surgeons decide on PAM strategy and consider themselves solely responsible for this. However, if surgeons omit this, the nurse CM will remind them to or, if the case is straightforward, select a strategy using her personally developed protocol.	Surgeons and cardiologists consider themselves responsible to select a PAM strategy at their team meeting, but, in practice, the PA/registrar mostly selects an anticoagulation strategy according to the departmental protocol.
Resources		
	• Patient records, referral letters, medication list • Booking sheet (also via e-mail) • Preoperative screening results • Pre-admission booklet • Instructions by NUM • NUM's notebook, surgery board • Asking patient (upon admission)	• Patient records, referral letters, medication list (verified by pharmacy assistant) • Heart team meeting form • Preoperative letter • Secretary's patient lists • Asking the patient (clinic, admission)
Protocols	Surgeons use their knowledge of international guidelines, and nurse CM uses own protocol.	Departmental (2-page) protocol based on guidelines,* used by registrars/PAs and surgeons.
Patient instructions		
Verbal	• Surgeon, nurse CM, clinic nurses	• PA/registrar, secretary (over phone)
Written	• Prescription (if indicated) • Instruction letter; pre-admission booklet	• Prescription (if indicated)
Signalling abnormalities†		
Outpatient setting	If the clinic nurse notices that PAM strategy is unclear (e.g. mixed information), she consults nurse CM.	The anesthetist (at clinic) or secretary may notice that a missing, unclear or unusual PAM strategy, and contact the surgeon, registrar or PA.
Inpatient setting	If the NUM signals abnormalities during pre-admission checks or admission, she notifies the surgeon or, in case of low platelet levels, the anesthetist.	If the PA/registrar signals abnormalities during preparations or upon admission, a proper response will be discussed the surgeon.
Signalling channels (least to most urgent)	face-to-face (e.g. ward rounds) > e-mail > texting > phone.	Face-to-face (e.g. clinic or during afternoon handoffs) > phone.
Individual systems		
	• NUM developed system for pre-admission checks (notebook, surgery board, EHR notes, and mental checklist) • Nurse CM developed protocol for PAM strategy based on local experience.	• Locally developed departmental protocol for PAM based on guidelines • Secretary developed own checklist to list patient information to guide phone calls

CM, case manager. *EHR*, electronic health record. *NUM*, nurse unit manager. *PAM*, preoperative anticoagulation management. *PA*, physician assistant.

* Guidelines include ACCP 2012; ESC/EACTS 2014; ESC 2016. † Response to abnormalities is identical at both sites: a reversal agent (e.g. vitamin K) or platelets will be administered to ensure values within an appropriate range for surgery. If not effective or not possible, the surgery is postponed.

Figure 2. Work-as-done model of preoperative anticoagulation management in the Australian hospital.



Anticoag, anticoagulation therapy. *HCPs*, healthcare professionals. *MDT*, multidisciplinary team meeting. *Nurse CM*, nurse case manager. *NUM*, nurse unit manager. *PAM*, preoperative anticoagulation management. *Pt*, patient. *Surg*, surgery. *Wks*, weeks.
Involved professionals (function in model): surgeon (1/8); nurse CM (2); pre-admission clinic nurse (3); patient (4); NUM (5/6); anesthetist (7).

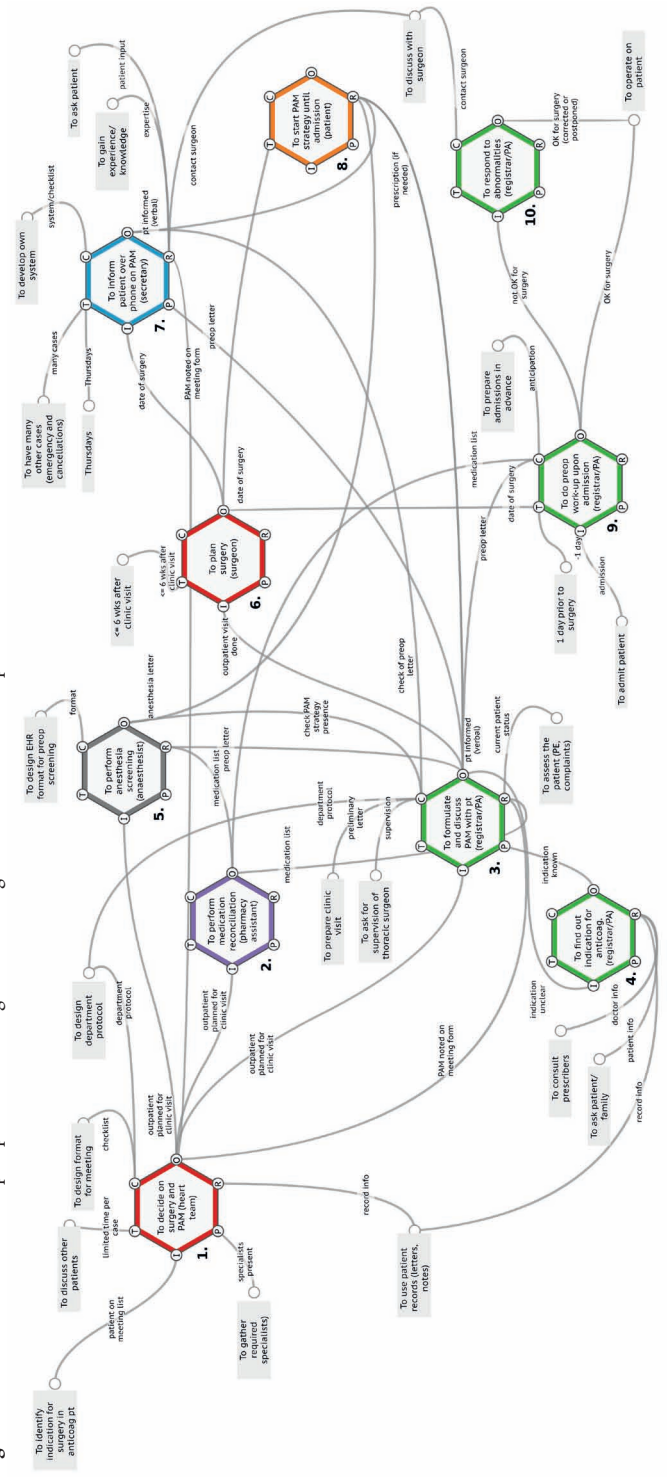


Figure 3. Work-as-done model of preoperative anticoagulation management in the Dutch hospital.

Anticoag, anticoagulation therapy. *PA*, physician assistant. *PAM*, preoperative anticoagulation management. *Preop*, preoperative. *Pt*, patient. *Wks*, weeks.
Involved professionals (function in model): surgeon (and cardiologist) (1/6); registrar or PA (3-4/9-10); pharmacy assistant (2); anesthetist (5); secretary (7); patient (8).

if straightforward, selects a strategy based on a self-developed protocol. The patient also receives an instruction letter, and prescriptions for bridging therapy if required. Lastly, the nurse e-mails a 'booking sheet' with patient, surgery, and PAM details to the pre-admission clinic, admission wards, anesthetists, and operating theaters.

3. **To conduct intake at pre-admission clinic:** two to three weeks prior to surgery, patients visit the hospital again for a preoperative screening with several tests. At this pre-admission clinic, a nurse checks whether the patient received and understood the PAM strategy. If unclear, the clinic nurse contacts the nurse CM *(function 2)* to provide the patient with PAM instructions.
4. **To start selected PAM strategy up until admission:** at home, patients are expected to adhere to the PAM strategy.
5. **To conduct pre-admission checks:** in preparation for the following week's surgeries, the nurse unit manager (NUM) of the admission ward retrieves the preoperative screening results from the electronic health record (EHR) and PAM strategies from booking sheets. If the NUM identifies anticoagulation-related abnormalities, the surgeon and/or anesthetist will be texted or called. The NUM notes all patient details, including PAM strategy, in a personal notebook (Figure 4) and on the 'surgery board' (i.e. white board on the ward). The NUM usually admits patients, but provides electronic instructions for colleagues if this is not the case (e.g. weekends).

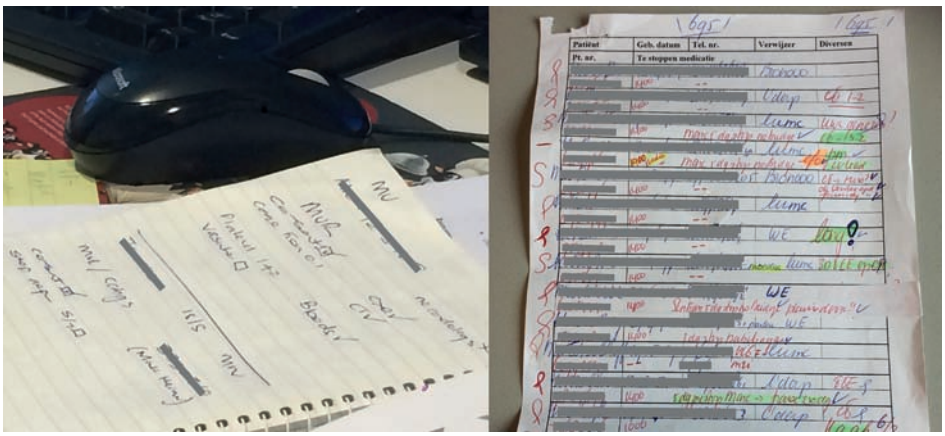


Figure 4. Photographs of naturally developed individual systems of Australian nurse unit manager (left) and Dutch planning office secretary (right)

6. **To perform work-up:** upon patient admission the night before surgery, the NUM determines whether patients adhered to the PAM strategy by asking and by assessing International Normalized Ratio (INR) and platelet levels.
7. **To conduct an anesthetic work-up:** the work-up of the anesthetist also includes a check of anticoagulation medication and INR.

8. **To respond to abnormalities:** if patients did not adhere to the PAM strategy and/or the INR is not within the appropriate range, the NUM notifies the surgeon (Table 2), who decides whether or not to administer a reversal agent (e.g. vitamin K) or postpone the surgery. If platelet levels are too low, the nurse texts or calls the anesthetist, who can decide on administering extra platelets so that surgery can proceed.

Dutch model

The Dutch model (Figure 3) is comprised of 10 main functions:

1. **To decide on surgery and PAM**: the cardiothoracic surgeon and interventional cardiologist discuss treatment options for referred patients in a daily 'heart team meeting'. They document their decisions, including a PAM strategy, in the EHR. Surgical patients are scheduled for a one-day preoperative clinic visit with various clinicians in a fixed order (functions 2-5).
2. **To perform medication reconciliation**: a pharmacy assistant ensures an up-to-date medication list in the EHR.
3. **To formulate and discuss PAM with the patient:** patients consult a registrar or physician assistant (PA) (alternating shifts), who provides them with verbal instructions on the PAM strategy and prescriptions if needed. All required preoperative actions are noted in a 'preoperative letter' in the EHR (not provided to patients). Often, no PAM strategy has been selected or documented by the 'heart team' (function 1), in which case the registrar or PA selects a strategy according to the departmental protocol and, if needed, supervision from the attending surgeon (Table 2).
4. **To find out the indication for anticoagulation therapy**: to select the appropriate PAM strategy, the registrar or PA revisits the patient's indication for anticoagulation therapy, which can be obtained from the patient, EHR or by consulting the prescribing specialist by telephone or e-mail. Patients subsequently visit the surgeon, but this consult serves to educate patients on the surgery rather than PAM.
5. **To perform pre-anesthesia screening:** the anesthetist conducts a screening and provides patients with a letter that includes a medication list with preoperative instructions. For anticoagulation therapy, however, this is no more detailed than 'stop in consultation with surgeon'.
6. **To plan surgery:** a surgeon schedules the following week's surgeries and informs the planning office. Surgeries are planned at least five days in advance, unless vacant spots have to be filled.
7. **To inform patients**: the planning office informs patients over the phone about their exact date of surgery in the upcoming week, and any required preoperative actions, such as a PAM strategy. Phone calls are guided by information in the preoperative letters (function 3), and if necessary, digital meeting forms (function 1). One of the secretaries developed

a checklist to guide this process (Figure 4). If surgeries are rescheduled, the secretary informs patients in a similar fashion.

8. **To start the selected PAM strategy:** At home, patients are expected to adhere to the PAM strategy.
9. **To perform work-up:** upon admission the day before surgery, the registrar or PA determines whether patients adhered to the PAM strategy and performs appropriate testing (e.g. INR), according to notes in the preoperative letter (function 3) and/or the medication list. Platelet levels are tested at the clinic (function 2) and only repeated if six or more weeks have passed.
10. **To respond to abnormalities:** registrars or PAs respond to abnormalities (e.g. elevated INR) after discussing with the surgeon whether or not to administer a reversal agent or to postpone surgery.

Variability and interdependence

In the Dutch setting, variability became particularly apparent for function 1, as registrars and PAs mentioned that the team meeting mostly did not produce a PAM strategy. Similarly, the Australian nurse CM often selected a PAM strategy if the surgeon omitted to note this in the pre-admission booklet. In complex cases, the nurse CM would consult the surgeon, which is similar to Dutch registrars/PAs who may ask for supervision from the surgeon.

At both sites, functions 1-3 provided outputs that served as important resources for several 'downstream' functions. These functions generated documents that served important roles later on, namely the Australian booking sheet (output of function 2; input for 3/4) and the Dutch preoperative letter (output of function 3; resource for 5; precondition for 7; control for 9) (Figures 2 and 3).

Both models also included downstream functions that controlled upstream functions. The Australian nurse CM could remind surgeons to fill out a PAM strategy (i.e. function 2 controlling 1), and the clinic nurse consulted the nurse CM if the PAM strategy was unclear (i.e. function 3 controlling 2). Both Dutch anesthetists (function 5) and secretaries (function 7) could signal a missing or incomplete preoperative letter, thereby controlling function 3.

Interdependence was particularly apparent for Dutch function 3, linked to as many as five other foreground functions (i.e. 1, 2, 4, 5 and 7) (Figure 3). Remarkably, there were two similar, partially overlapping functions (7 and 8) for work-up upon admission in Australia causing duplicate measurements of INR (Figure 2).

The functions that represented patients adhering to the PAM strategy (Australian function 5; Dutch function 8) appeared to have no formal 'input' or 'active agent' to start this function, and hence seemed to depend solely on the patient's memory and support from verbal and/or written instructions.

DISCUSSION

This study was the first to use a Safety-II approach and FRAM in the context of medication management in healthcare. This provided insight into the complex process of preoperative anticoagulation management 'as-done' and 'as-imagined' in two international contexts. This process differed substantially between the study sites, both in practical organization and disciplines involved. While, in both centers, 'work-as-done' at the front line differed from 'work-as-imagined' in generic guidelines, both had developed control mechanisms to ensure successful PAM, such as critical review of a colleague's decisions and documents, and individual systems to enhance efficiency and thoroughness.

Work-as-done differed from the process 'as-imagined' by guidelines, which assumed that physicians, specifically anesthetists, play a central role in PAM. In both centers, however, this was the responsibility of surgical staff rather than anesthesia staff, with key roles assigned to (specialized) nurses or registrars/PAs. This may have practical purposes, as these disciplines also have a central role in inpatient care. Furthermore, in contrast to the national guideline,[44] the Dutch process did not involve anticoagulation services, usually responsible for outpatient anticoagulation management in the Netherlands. Instead, the department temporarily took over this responsibility to enhance clarity for patients. These examples illustrate how studying work-as-done might help to identify potential differences between local practices and guidelines, but also the pragmatic, practical reasons behind it. Moreover, this study revealed varying perceptions on roles and responsibilities among clinicians involved in anticoagulation management, which aligns with a recent survey study.[9] For example, interviewed surgeons felt responsible for formulating and documenting the PAM strategy, but other staff reported that this was often omitted in which case they made a decision.

Opportunities for improvement

While patients received various forms of information, both centers relied on the patient's memory to adhere to the PAM strategy at home. Modern information technology may provide solutions for a more active 'input' for this function, such as automated text messages on the day the patient has to stop anticoagulation. Simple written instructions, as used in Australia, could be developed in the Dutch department to offer a useful reminder for patients at home. Learning cuts both ways, as the Australian department might consider limiting the number of information sources as this also increases the risk of conflicting information. In addition, they may consider introducing a single-day multidisciplinary clinic with involvement of a pharmacy assistant, as used in the Dutch setting, in order to limit the number of hospital visits for patients and ensure accurate medication information.

Inaccuracies in, or unavailability of, documents produced in early functions to record the PAM strategy could negatively affect later steps in the process (e.g. informing the patient). In these situations, the identified control mechanisms may prove their value, e.g. other staff

may select a PAM strategy if omitted in function 1. While this illustrates clinicians' profound adaptive skills, it may also result in habituation to the fact that this information is missing, decreasing use of this resource. Therefore, there should be clear agreements on what can be expected from staff carrying out these functions. Individual staff had naturally developed some of these control mechanisms, such as a checklist or notebook. While these are likely to support thoroughness, they may also pose safety risks when key persons are absent or replaced and colleagues are unfamiliar with these methods. To illustrate, the Dutch secretary seemed to view her checklist as a 'personal aid' and did not plan on transferring this method to new staff members. Hence this potentially valuable control mechanism may be jeopardized because of its individual and not structural nature.

Practical implications and usability

FRAM appeared to be a promising tool that can be readily applied to study a multidisciplinary medication management process, and identify functions that are important for success. The workload of FRAM, collaboratively was estimated to be about 47 hours per site (Table 1), which is comparable to the workload associated with traditional methods, such as a root cause analysis (RCA).[47] In line with a previous study,[37] clinicians seemed to easily understand the relevance, background, and design of FRAM. Reflection meetings with staff were considered insightful and raised awareness of interdependencies between activities of colleagues. For example, Dutch senior staff questioned whether anesthetists could actually signal a missing or incorrect PAM strategy, but a junior registrar confirmed that he had experienced this occasionally. Staff also used the model to discuss opportunities for improvement, such as the redundancy in the Australian work-up upon admission. This way, FRAM may be used to reconcile and improve the synergy between the world of guidelines and systems design (work-as-imagined) and the world of everyday clinical practice (work-as-done). FRAM could also be used as a support tool for incident analyses because it allows studying how an event emerged in relation to work-as-done rather than only comparing such events with expectations of a process (e.g. protocols).[39] A unique feature of FRAM is that it does not need to be triggered by an incident, as it can be used proactively to gain understanding of work-as-done. This could potentially respond to recent calls for greater proactivity and a greater focus on what goes right in patient safety improvement.[48] Future studies could seek to combine more quantitative analyses with qualitative FRAM models, for example, to measure defined outputs of functions with statistical process control[49] or to quantify functions' variability so that probability simulations can be applied.[50]

Study strengths and limitations

To our knowledge, this is the first study to study a medication management process 'as-imagined' and 'as-done'. A specific strength of the method is its focus on activities that are responsible for the fact that clinical work usually goes right rather than specific situations

where things go wrong. Studying work-as-done offers a way forward for patient safety, which under the traditional Safety-I domain is mainly focused on complications or incidents, which are very important — but also very specific, and often rare.[21,27] This study has international applicability as it showed that visualization of work-as-done using FRAM can be used to study and compare challenges and strengths in two international contexts. While the multicenter context is also an advantage, both sites were cardiothoracic surgery departments at teaching hospitals, which may limit generalizability to other units. More research in other settings is warranted, as PAM is also common practice for other specialties. Moreover, real practice may still differ from the models developed in this study as we did not use direct observations,[51] and the purposive sampling strategy may introduce the risk of selecting a subgroup or network of professionals, which could be prevented with random samples in future studies. In mitigation, and in accordance with qualitative research guidelines,[52] we used data saturation to increase the ability to identify the most relevant functions and interdependencies.

CONCLUSIONS

This study provided a deeper understanding of anticoagulation management in practice and in relation to guidelines. FRAM appeared to be an insightful tool, suitable for studying complex healthcare processes, such as medication management, identifying functions that are important to ensure the process functions as intended, including their interdependence and variability. In addition, this proactive approach revealed the opportunities for improvement and the presence of naturally developed individual systems, which otherwise remained undetected. Future studies are warranted to investigate PAM as well as the applicability of FRAM in other healthcare contexts.

Acknowledgement

We like to thank all healthcare professionals who were willing to reflect on the process so openly in the interviews and department meetings.

LIST OF ABBREVIATIONS

CM, case manager
EHR, electronic health record
FRAM, functional resonance analysis method
INR, international normalized ratio
NUM, nurse unit manager
PA, physician assistant
PAM, preoperative anticoagulation management

REFERENCES

1. Wysowski DK, Nourjah P, Swartz L. Bleeding Complications With Warfarin Use A Prevalent Adverse Effect Resulting in Regulatory Action. *Arch Intern Med*. 2007;167:1414-9.
2. Gomes T, Mamdani MM, Holbrook AM, et al. Rates of hemorrhage during warfarin therapy for atrial fibrillation. *CMAJ* 2013;185:E121-7.
3. Bates DW, Cullen DJ, Laird N, et al. Incidence of Adverse Drug Events and Potential Adverse Drug Events Implications for Prevention. *JAMA* 1995;274:29-34.
4. Budnitz DS, Lovegrove MC, Shehab N, et al. Emergency Hospitalizations for Adverse Drug Events in Older Americans. *N Engl J Med* 2011;365:2002-12.
5. Hakkarainen KM, Gyllensten H, Jönsson AK, et al. Prevalence, nature and potential preventability of adverse drug events - A population-based medical record study of 4970 adults. *Br J Clin Pharmacol* 2014;78:170-83.
6. Damen NL, Baines R, Wagner C, et al. Medication-related adverse events during hospitalization: a retrospective patient record review study in The Netherlands. *Pharmacoepidemiol Drug Saf* 2017;26:32-9.
7. Nielsen VG, Asmis LM. Hypercoagulability in the perioperative period. *Best Pr Res Clin Anaesthesiol* 2010;24:133-144.
8. Wysokinski WE, McBane RD. Periprocedural bridging management of anticoagulation. *Circulation* 2012;126:486-90.
9. Flaker GC, Theriot P, Binder LG, et al. Management of Periprocedural Anticoagulation: A Survey of Contemporary Practice. *J Am Coll Cardiol*. 2016;68:217-226.
10. NHS Herts Valleys Commissioning Group. Hertfordshire guidelines for oral anticoagulation of patients with non-valvular AF. UK: 2016. *UK*. 2016. Available at: http://hertsvalleysccg.nhs.uk/publications/pharmacy-and-medicines-optimisation/local-decisions/cardiovascular-system/anticoagulants/3206-af-treatment-guideline-long-december-2015/file. Accessed January 29, 2018.
11. Dutch Health Care Inspectorate. *Anticoagulant Care Chain Not Sufficiently Sound* (Dutch). The Hague, the Netherlands; 2010. Available at: http://www.sin-nl.org/pdfs/igz_rapport_keten_trombosezorg_niet_sluitend_okt._2010.pdf. Accessed January 29, 2018.
12. Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS: the task force on myocardial revascularization of the European Society of Cardiology (ESC) developed with the special contribution of the European Heart R. *Eur Hear J* 2016;37:2893-962.
13. You J, Singer D, Howard P, et al. Antithrombotic Therapy for Atrial Fibrillation: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141:e531S-75S.
14. Heidbuchel H, Verhamme P, Alings M, et al. Updated European Heart Rhythm Association practical guide on the use of non-vitamin-K antagonist anticoagulants in patients with non-valvular atrial fibrillation: Executive summary. *Eur Hear J* 2017;38:2137-49.
15. Keeling D, Tait RC, Watson H, British Committee of Standards for Haematology. Peri-operative management of anticoagulation and antiplatelet therapy. *Br J Haematol*. 2016;175:602-13.
16. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Thorac Cardiovasc Surg*. 2014;148:e1-132.
17. Tompkins C, Cheng A, Dalal D, et al. Dual Antiplatelet Therapy and Heparin "Bridging" Significantly Increase the Risk of Bleeding Complications After Pacemaker or Implantable Cardioverter-Defibrillator Device Implantation. *J Am Coll Cardiol* 2010;55:2376-82.

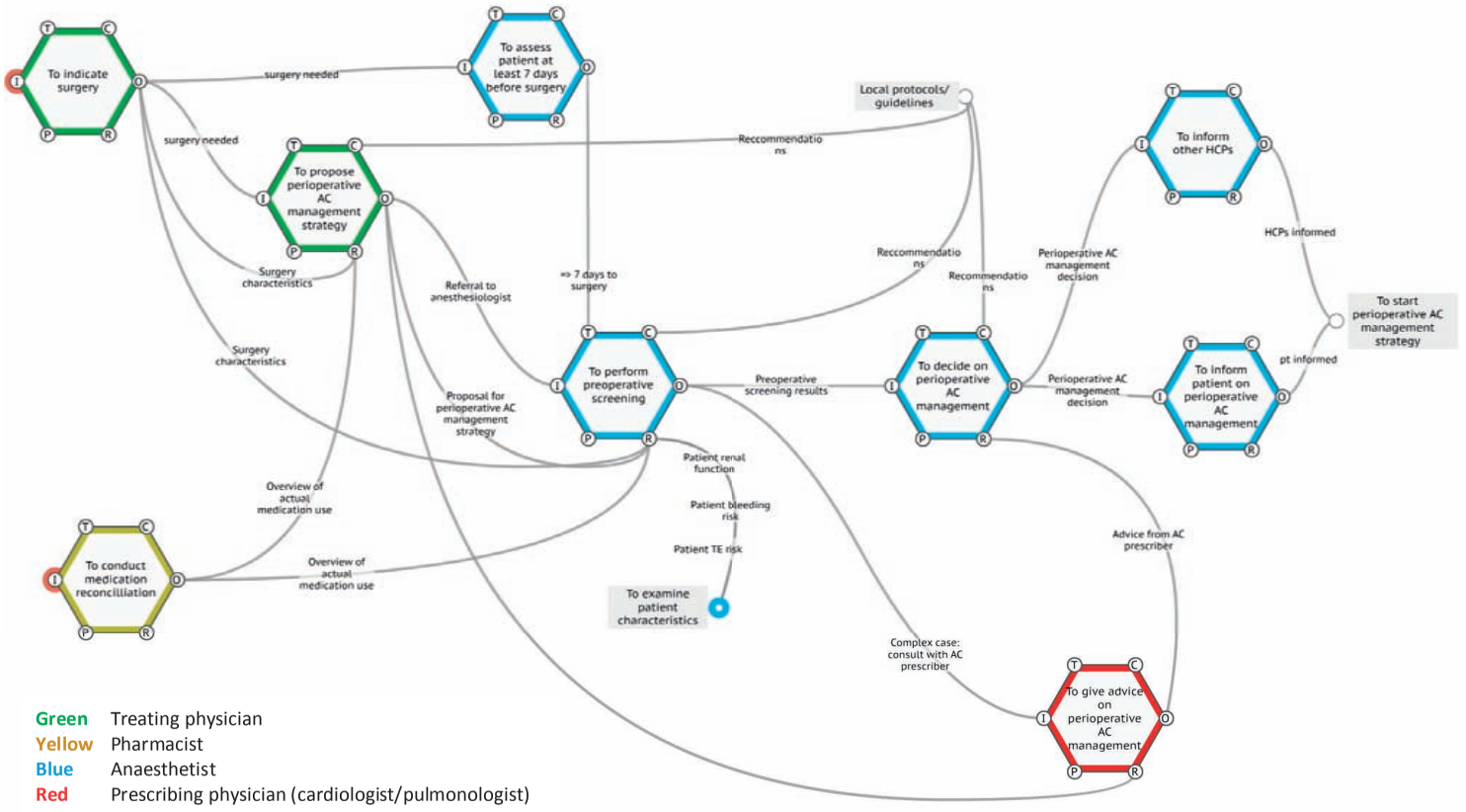
18. Eijgenraam P, ten Cate H, ten Cate-Hoek AT. Practice of bridging anticoagulation: Guideline adherence and risk factors for bleeding. *Neth J Med* 2014;72:157-164.
19. Steinberg BA, Kim S, Thomas L, et al. Lack of concordance between empirical scores and physician assessments of stroke and bleeding risk in atrial fibrillation: Results from the outcomes registry for better informed treatment of atrial fibrillation (ORBIT-AF) registry. *Circulation* 2014;129:2005-12.
20. Damen N, Damen P, van Dijk L, et al. *Implementation of the National Standard Anticoagulation Chain (V2.0): Current State of Affairs (Dutch).* Utrecht, the Netherlands; 2015. Available at: https://www.nivel.nl/sites/default/files/bestanden/Rapport-quickscan-implementatie-LSKA.pdf?. Accessed January 29, 2018.
21. Hollnagel E. *Safety-I and Safety-II. The Past and Future of Safety Management.* Farnham, UK: Ashgate Publishing Limited, 2014.
22. Lawton R, Taylor N, Clay-Williams R, Braithwaite J. Positive deviance: a different approach to achieving patient safety. *BMJ Qual Saf* 2014;23:880-3.
23. Baxter R, Taylor N, Kellar I, Lawton R. What methods are used to apply positive deviance within healthcare organisations? A systematic review. *BMJ Qual Saf* 2016;25:190-201.
24. Scerri A, Innes A, Scerri C. Discovering what works well: Exploring quality dementia care in hospital wards using an appreciative inquiry approach. *J Clin Nurs* 2015;24:1916-25.
25. Kelly N, Blake S, Plunkett A. Learning from excellence in healthcare : a new approach to incident reporting. *Arch Dis Child* 2016;101:788-91.
26. Hollnagel E, Wears R, Braithwaite J. From Safety-I to Safety-II: A White Paper. Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.; 2015. Available at https://resilienthealthcare.net/wp-content/uploads/2018/05/WhitePaper-Final.pdf Accessed January 29, 2018.
27. Braithwaite J, Wears RL, Hollnagel E. Resilient health care: Turning patient safety on its head. *Int J Qual Heal Care* 2015;27:418-420.
28. Hollnagel E, Braithwaite J, Wears RL. Resilient Health Care. Farnham, England: Ashgate Publishing Limited, 2015.
29. Grol R, Wensing M. Effective implementation of change in healthcare: a systematic approach. In: Grol R, Wensing M, Eccles M, Davis D, Eds. Improving Patient Care: The Implementation of Change in Health Care. Oxford, UK: John Wiley & Sons, Ltd, 2013:40-63.
30. Hollnagel E. FRAM: The Functional Resonance Analysis Method. Modelling Complex Socio-Technical Systems. Surrey, UK: Ashgate Publishing Limited, 2012.
31. Nouvel D, Travadel S, Hollnagel E. Introduction of the Concept of Functional Resonance in the Analysis of a Near-Accident in Aviation. Introduction of the Concept of Functional Resonance in the Analysis of a Near-Accident in Aviation. 33rd ESReDA Seminar: Future challenges of accident inv. In: *33rd ESReDA Seminar: Future Challenges of Accident Invesitgation*. Ispra, Italy, 2007. Available at: https://hal-mines-paristech.archives-ouvertes.fr/hal-00614258/document. Accessed January 29, 2018.
32. Woltjer R. Functional Modeling of Constraint Management in Aviation Safety and Command and Control [Doctoral thesis]. 2009. http://liu.diva-portal.org/smash/get/diva2:210824/FULLTEXT01.pdf. Accessed August 22, 2017.
33. De Carvalho PVR. The use of Functional Resonance Analysis Method (FRAM) in a mid-air collision to understand some characteristics of the air traffic management system resilience. *Reliab Eng Syst Saf* 2011;96:1482-98.
34. Belmonte F, Schön W, Heurley L, et al. Interdisciplinary safety analysis of complex socio-technological systems based on the Functional Resonance Accident Model: An application to railway traffic supervision. *Reliab Eng Syst Saf* 2011;96:237-49.

35. Amorim AG, Pereira CMNA. Improvisation at Workplace and Accident Causation - An Exploratory Study. *Procedia Manuf* 2015;3:1804-11.
36. Rosa L, Haddad A, de Carvalho P. Assessing risk in sustainable construction using the Functional Resonance Analysis Method (FRAM). *Cogn Technol Work* 2015;17:559-73.
37. Clay-Williams R, Hounsgaard J, Hollnagel E. Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implement Sci* 2015;10:125.
38. Raben DC, Bogh SB, Viskum B, at al. Learn from what goes right: A demonstration of a new systematic method for identification of leading indicators in healthcare. *Reliab Eng Syst Saf* 2018;169:187-98.
39. Hounsgaard J. Patient safety in everyday work. Learning from what goes right [MSc thesis]. University of Southern Denmark; 2016. http://functionalresonance.com/onewebmedia/Hounsgaard%20(2016).pdf. Accessed January 29, 2018.
40. Hollnagel E, Hounsgaard J. FRAM – The Functional Resonance Analysis Method – A Handbook for Practical Use of the Method. Middelfart, Denmark; 2014. Available at: http://functionalresonance.com/onewebmedia/FRAM_handbook_web-2.pdf. Accessed January 29, 2018.
41. Resilient Health Care Net Meeting. Available at: http://resilienthealthcare.net/meetings/index.html. Accessed August 23, 2017.
42. FRAMily meeting. Available at: http://functionalresonance.com/framily-meetings/index.html. Accessed January 29, 2018.
43. Douketis J, Spyropoulos A, Spencer F, et al. Perioperative Management of Antithrombotic Therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141:e326S-50S.
44. Dutch National Steering Committee on Chain of Antithrombotics Care. Dutch National Standard Chain of Care on Antithrombotics – Version 2.0 (Dutch). Utrecht, the Netherlands; 2014. Available at: https://www.knmp.nl/patientenzorg/samenwerking/landelijke-standaard-keten-antistolling-2-0-lska. Accessed August 22, 2017.
45. Hill R. FRAM Model Visualiser. version 0.4.1. Available at: http://functionalresonance.com/the%20fram%20model%20visualiser/index.html Accessed January 29, 2018.
46. Mason M. Sample Size and Saturation in PhD Studies Using Qualitative Interviews. *Forum Qualitative Sozialforschung / Forum: Qualitative Social Research* 2010. doi: 10.17169/fqs-11.3.1428.
47. Taitz J, Genn K, Brooks V, et al. System-wide learning from root cause analysis: a report from the New South Wales Root Cause Analysis Review Committee. *Qual Saf Health Care* 2010;19:e63.
48. Hounsgaard J. Using FRAM as a Quality Improvement Tool in Health Care. In: *The FRAMily Meeting*. Munich, Germany; 2013.
49. Patriarca R, Di Gravio G, Costantino F. A Monte Carlo evolution of the Functional Resonance Analysis Method (FRAM) to assess performance variability in complex systems. *Saf Sci*. 2017;91:49-60. doi:10.1016/j.ssci.2016.07.016.
50. Feeley D. Six Resolutions to Reboot Patient Safety. Institute for Healthcare Improvement. Available at: http://www.ihi.org/communities/blogs/_layouts/15/ihi/community/blog/ItemView.aspx?List=7d1126ec-8f63-4a3b-9926-c44ea3036813&ID=365&Web=1e880535-d855-4727-a8c1-27ee672f115d. Published 2017. Accessed September 1, 2017.
51. Catchpole K, Neyens DM, Abernathy J, et al. Framework for direct observation of performance and safety in healthcare. *BMJ Qual Saf* 2017;26:1015-21.
52. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Heal Care*. 2007;19:349-57.

Appendix 1. Topic list used during interviews to identify aspects and coupling of FRAM functions.

Aspects	Questions
Input	What starts the function? What does the function act on or change?
Output	What is the output or results of the function? Do you have to inform anyone? Do you have to collect or record/report anything? If so, where? Who needs the output? Who will use what is produced? Have you agreed with whoever uses this that it is what they need?
Precondition	What should be in place so that you can complete the function normally? What do you do if the preconditions are not available?
Resource	What resources do you need to perform the function, such as people, equipment, IT, power, buildings, etc.? What do you do if the resources are not available?
Control	Do you have any goals for the function, such as do something within a time frame (this is a control)? What is the purpose of this function? Why do we do this? Do you have formal procedures or instructions controlling the function? Do you have people, such as supervisors, controlling the function? Are there values controlling the function? Do unofficial work practices or culture control the function? Do you have priorities, such as a triage system? Are there constraints such as budget?
Time	Is there any time related to the function? Is there a certain time where you have to perform the function? What happens if you are delayed— will you still do the function or not and what is the consequence for the following functions? Time only has four options: too early, too late, on time, or not at all.

Appendix 2. FRAM model of preoperative anticoagulation management as stipulated by guidelines (i.e., work-as-imagined).



Chapter 10

A perspective on applying Just Culture and Safety-II principles to improve learning from sentinel events in healthcare

MS de Vos, SWA Dekker, L den Dijker, JF Hamming

based on

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ABSTRACT

Just Culture and Safety-II are gaining increased attention in healthcare, but it remains a challenge to translate these into clinical practice. Both provide principles that could be applied to how we learn from sentinel events as well as from things that go right; and how we deal with and care for those involved. This paper reflects on how to apply these principles and presents a different set of questions to focus on collective recovery, restoration and forward-looking accountability, rather than on individual culpability. We need to move away from a primary focus on culpability and retribution, instead directing attention to both first and second victims' hurts and needs. A most common need is the reassurance that the institution and those involved learn from the event and prevent recurrence. Subsequent learning reviews aim to shed light on the sources of resilience that make everyday practice usually go right, so that this can be enhanced. Together, Just Culture and Safety-II provide valuable guidance to improve learning from sentinel events, specifically by adding empathy, nuance and a sense of practical reality that facilitate restoration of those involved, and improvement processes. Research is warranted to further explore the benefits of applying these principles in the aftermath of sentinel events in healthcare.

Key words: patient safety; continuous quality improvement; sentinel events; Just Culture; Safety-II.

JUST CULTURE AND SAFETY-II: NEED FOR PRACTICAL GUIDANCE

The concept of Just Culture, focused on harnessing a culture of trust and learning without blame, has gained increased attention in various industries and found its way to healthcare.[1] A Just Culture is difficult to build, as illustrated by a study revealing that many hospitals that are convinced to have established a 'blame-free' culture, also reported that culpability was of primary concern in their investigations of sentinel events.[2] This suggests that crucial aspects of Just Culture, such as that a safe, blame-free environment is an essential precondition for learning, may not be fully understood or really difficult to implement. A similar example can be found in a recent framework for accountability in healthcare.[3] While this framework attempts to incorporate Just Culture principles, it stipulates that the first question to be addressed after a patient safety incident is whether staff members' actions were "malicious" and "intended to cause harm" to patients.[3] This reflects a culture of mistrust rather than a Just Culture. Besides theories about culture, proactive approaches to safety are beginning to find their way to healthcare. An example is 'Safety-II', which focuses on facilitating things going right rather than preventing specific things going wrong.[4] This novel approach to safety is promising, but greater adoption requires practical proposals for implementing its principles in healthcare practice.

This article assesses how Just Culture and Safety-II principles can be applied to enhance investigations of sentinel events or other serious and harmful events in healthcare. A framework with a practical set of questions, drawn from the Just Culture and Safety-II literature, is presented to guide the process of learning from sentinel events in healthcare.

Just Culture: victims first

A Just Culture balances safety and accountability, particularly in the aftermath of undesired events, such as sentinel events. Important aspects of a Just Culture include learning from mistakes without a focus on blame, as well as systems improvement instead of individual punishment. One of the first challenges one faces following a sentinel event, is the tendency to hold someone accountable for the situation (*retribution*), while there is also a great need to work on recovery for the future (*restoration*). Just Culture theory stipulates that learning and punishment are not a good match. If learning is the primary objective, such as in sentinel event investigations in healthcare, the focus should not be on retrospective culpability or retribution, but rather on forward-looking accountability, which includes everyone's tasks and responsibilities in the aftermath of the event.[1,5]

Shifting focus from retribution to restoration

Traditional proposals for a Just Culture suggest being clear about 'the line' between acceptable and unacceptable behavior. Many believe, for instance, that a question of culpability remains appropriate in case of 'reckless behavior'.[2] Recklessness and negligence are judicial terms,

Table 1. Phases and questions, based on Just Culture and Safety-II principles, to guide the process of sentinel event investigation in healthcare.

Phase and questions	***Related concept***
I. Serious event (e.g. sentinel event, serious incident/adverse event)	
II. Victims first	
- Who is hurt?* - What are their needs?* - Who should meet those needs (e.g. who talks to the patient and family, who takes care of colleagues involved, who else should be informed)?	*Just Culture: restorative approach, forward-looking accountability*
III. Shifting the focus from culpability to learning	
- Acknowledging the shared need for learning from the event - What, instead of who, contributed to this event?	*Just Culture: blame and a focus on culpability hamper learning*
IV. In-depth investigation	
- How does this process usually go right?	*Safety-II: understanding how this usually goes right as a basis for understanding the event*
- How do we imagine this process to be? What do we expect or how is it designed? For example, are there any work instructions or 'rules' in place, and how legitimate, morally sound and workable are these? ‡	*Safety-II: work-as-imagined*
- How is this process carried out in everyday practice? Are there any discrepancies with work-as-imagined?	*Safety-II: work-as-done*
- How does the event relate to work-as-imagined/-done? Can we use these insights to understand how this could have happened?	*Safety-II: specific event in relation to work -as-imagined/-done §*
V. What can we learn from this event, and how can we improve? ||	*Just Culture: forward-looking acccountability;* *Safety-II: reconciling work-as-imagined and work-as-done, facilitating success*

* This includes all involved, i.e. patients and their families as well as all care providers or other staff. Hurt refers to injury in the broadest sense of the word, e.g. physical injury, psychological trauma, reputational damage. Needs could include physical care as well as for example the need that the organisation learns from the event or the need that certain questions are addressed during the investigation.

† Just Culture theory also discusses that those responsible for making judgments about deviations from regular procedures (i.e. the line between acceptable and unacceptable behavior or performance) need to be well acquainted with the work processes and in the context of real everyday practice.

‡ For example, are there any goal conflicts or conflicting expectations?

§ Visualization of the work process, e.g. using the Functional Resonance Analysis Method (FRAM), reveals interdependencies and interactions between various activities (e.g. the physical exam and blood loss monitoring steps may affect the decision whether or not to test hemoglobin level). Moreover, these visual models can be used to study the event as a scenario within the more generic work process.

|| Reflective dialogue with staff and management to discuss what adjustments can be made to make success more likely. For example, how could work-as-imagined and work-as-done be reconciled? What expectations cannot be met in everyday practice, and why? Are there any activities that require an adaptive capacity from staff that is unrealistic or unfeasible, and how could this be organized differently? How reliable are outputs of activities (e.g. documents, measurements) that serve as the input for another activity?

however, and not psychological categories or clinical behaviors. It will always be difficult, disputable and context-dependent to differentiate between unacceptable and acceptable behavior.[5] The line between tolerable and culpable behavior is not fixed a priori. Instead, it needs to be drawn time and again by those with the position, capacity and responsibility to do so, and it is ultimately based on a host of subjective judgments about supposedly 'normal' clinical standards, practices, as well as prudence, foresight or expectations. In other words, there really is no line, there are only people who draw it.

A retributive approach is characterized by questions such as: 'Which rule is broken?'; 'Who did that?'; and 'How severe is that breach?'.[5] These judgments will be strongly affected by knowledge of the (severity of the) outcome (*outcome bias*), and the distortive effects of *hindsight bias* (i.e. perceived probability of events in retrospect) and *outside bias* (i.e. related to the position of observer instead of actor).[1] Moreover, the perspective of someone who judges a situation from an external, bird's eye perspective, such as during the case reconstructions in sentinel event investigations, will always be different from the perspective of the clinicians who faced the clinical dilemmas.

Retribution can satisfy some demands, but there is much to lose. Retribution is a process between two parties, mostly removed from the rest of the community and the victim(s). Openness to different accounts of what happened is easily sacrificed in an adversarial setting where one account wins, and one account loses. Patients and professionals involved may feel left out, sidelined, without much of a voice. Retributive approaches can also encourage 'offenders' to look out for themselves, and discourage them from acknowledging their responsibility out of fear of self-incrimination. Not much of value might be learned; not many systemic improvements may follow from retributive justice.

Looking after all victims

An alternative response following a sentinel event, or other events that clinicians and/or patients consider serious and important, is to focus on hurts, on what is needed to restore the damage, trust and relationships, and on who has the obligation to help meet those needs.[5] This approach gives rise to the following questions (Table 1, box II):

- Who is hurt?
- What are their needs?
- Who should meet those needs?

The 'who is hurt' question calls attention to those who have been damaged, in the broad sense of the word (e.g. physically, mentally) (Table 1, box II). This includes the patient and the family, but also the healthcare professionals, commonly referred to as 'second victims'.[6–9] Thereby, this approach aligns with second victim or peer support programs that are increasingly implemented in healthcare.[10] To illustrate, it was our local experience that patients and families were often told to await formal investigation of the event, with too little attention to

their needs, such as early disclosure and apology. Recently, our surgical department put up a poster in the auditorium for daily meetings to remind everyone of the important steps in the first response to a sentinel event, such as 'who talks to the patient and family members?', and 'who takes care of the colleagues involved?'. A focus on recovery should be the first response, and should precede the in-depth investigation with staff interviews. In other words, 'victims first, analysis second'.

Can somebody, or some act, be beyond restoration?

Retributive theory believes that responding to hurt with more hurt will somehow equalize or even eliminate the injustice that has been inflicted. Restorative theory, instead, believes that pain requires healing. But clinicians, patients, even colleagues can all point to cases where they might feel a retributive response is the only appropriate one. This raises the question whether there cases where those who have inflicted the pain are beyond the reach of restorative justice?

It is not the case itself, nor its consequences, that determine whether it is beyond restoration. This is determined by our reading of, and judgment, about the case—which in turn are driven by the professional, organizational and cultural fore-structure of which we are part, and which we might well have helped create. It can be very difficult to determine how much responsibility individual professionals have when more system-level problems are in play, such as when admitting a patient to a ward that is understaffed. The important question is: who gets to decide whether a case is beyond the reach of restorative approaches, and what are their stakes (if any) in saying it is so?

Restorative theory should not be interpreted as a means to provide with immunity from prosecution of criminal behavior of professionals. Separate processes are, and should remain, in place to enable investigations of suspected criminal acts or misconduct in hospitals. The main objective in these investigations, however, is to answer questions from criminal law, whereas the main objectives in sentinel event investigations are learning and improvement. Therefore, these judicial questions do not have a place in the learning reviews that are started following severe incidents to prevent recurrence and improve the safety of future patients.

Promote restorative practices internally

Just Culture strives to restore the relationships that have been disturbed by the event, thereby trying to find a solution that meets the needs of all parties involved. Studies have shown that patients who experience harmful events or errors often want apologies, explanations and assurances that lessons are learned from their experience[11–13]– all of which could be achieved with a restorative rather than a retributive approach. It will likely require active effort to resist a natural tendency to search for a cause and to hold someone accountable. Staff, patients, and administrators may be less familiar with these theories and may still seek more traditional kinds of accountability. Not only investigation teams,[14,15] but also providers themselves are known to have a tendency to seek accountability, often resulting in self-blame.[6]

Finding ways to mitigate the negative aspects of retributive justice is essential to help others see responses as more 'just.' Whatever is done, ask who is hurt and give a voice to all involved. Identify responsibilities and obligations of various parties—not just the 'offender' or second victim. Try to socially embed your responses, so that the organization and its community feel part of the solution. External judicial authorities, as recently occurred in the UK[16] may come to a different conclusion from what the institution itself decided to do. While rare, this can of course put significant downward pressure on people's honesty and disclosure. This makes it even more important for hospitals themselves to have the courage to keep promoting restorative practices internally, as far as their discretionary space to do so stretches.

Two strategies, based on Just Culture principles, may help emphasize that recovery and learning are the primary objectives. First, the shared need for learning from the event could be emphasized and used as a starting point or trigger for an in-depth investigation (Table 1, box III). After all, the first and second victims may have different needs (e.g. treatment versus peer support), but all share the need that the hospital and its professionals learn from the event and that future recurrence is prevented.[5] Specifically, we could start asking patients and families, e.g. during disclosure conversations, if they have any specific questions or concerns that they would like to be addressed. Second, actively asking *what* instead of *who* was responsible may help to underline that solutions are sought at the system rather than individual level.

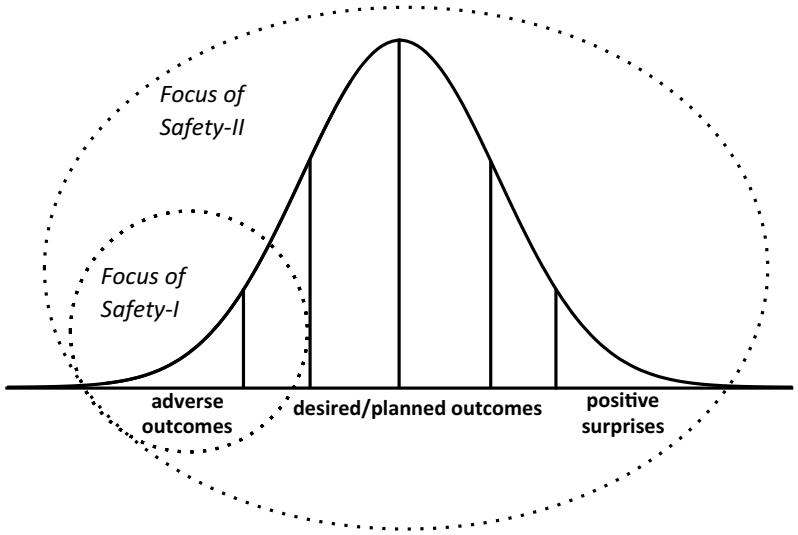
Safety-II: everyday practice as the basis for investigations

Once the hurts and needs of those involved have been identified in a way that is respectful to all the parties involved, an in-depth investigation can be initiated using the Safety-II approach (Table 1, box IV). This approach can be regarded as a natural extension of the current approach to safety (Safety-I), which is focused on negative outcomes, thus situations in which safety was *absent*. Safety-II expands the focus of learning because it aims to understand the ability to ensure safety, by examining how work processes in everyday practice usually go right, thus situations in which safety is *present* or 'created' (Figure 1).[4,17,18] This is based on the notion that greater understanding of how a process usually functions in everyday practice provides a better basis for understanding a specific occurrence (e.g. a sentinel event) as well as for finding ways to support the ability to achieve success.

Safety-II underlines that both desired and undesired outcomes result from the same underlying work process. This process may go right, as well as wrong, due to the natural variations in complex adaptive socio-technical systems (which include humans), and the resource limitations and goal conflicts that constantly operate within them. Flexibility and adaptability (*resilience*) are essential capacities to ensure success and safety, since work-as-imagined or planned seldom ends up being work-as-done. At the same time, these adjustments can be insufficient or unsuccessful and give rise to unsafe conditions or events.[17] By only assessing a sentinel event, it will be difficult to appreciate that certain deviations from protocols may also be present in everyday practice (e.g. because of trade-offs or goal conflicts), also in the many

cases with positive outcomes. When we identify a 'human factor' as root cause for a sentinel event, we fail to appreciate that this same factor more often has positive contributions, and has essential adaptive capacities in many other situations.[19] In short, Safety-II argues that to understand how 'safety' is ensured, we should not only assess the unsafe situations, but also how our professionals and systems manage to create safety in so many other cases (Figure 1).

Figure 1. The normal distribution of outcomes in everyday practices with the focus of Safety-I and Safety-II (adapted from Hollnagel[17]).



'The book' versus 'the messy reality'

Safety-II underlines that modern clinical practice is not linear but dynamic, and hence can no longer be reduced to neatly aligned domino tiles or cheese slices. Accordingly, the 'messy reality' of everyday practice may serve as a more realistic and representative starting point for sentinel event analysis than the single points in time that led to the undesired outcome. As an alternative to our efforts to prevent the *specific* type of event, we could invest in ensuring that this process goes *well*, which also entails that such negative events do not emerge.[4,17,18] This approach requires a different set of questions (Table 1, box IV) aiming to understand how the work is carried out in everyday practice, what capacities allow it to usually go right, and how this relates to expectations or protocols:

- How does this process usually go right?
- How do we imagine this process to be? (i.e. work-as-imagined)
- How is this process carried out in everyday practice? (i.e. work-as-done)

An analysis of work in everyday practice reveals gaps between work-as-imagined and work-as-done that are daily routine in clinical practice.[20] After all, clinical practice is not always 'by

the book', and can be full of unexpected and undesired conditions for which protocols (can) not always accommodate. In these situations, professionals adjust to match the situation.[4] These adjustments may be common and often result in good outcomes, but run the risk of being considered 'protocol violations' when examined without sufficient insight into everyday practice.

Interviews with the front line

Both Just Culture and Safety-II theory emphasize that input from the workforce is essential for identifying improvement strategies that are both effective and workable. Therefore, the questions that guide these investigations (Table 1, box IV) should be asked to those at the sharp end as well as leadership. This will not only help collect information that is unique to those who do the work on a daily basis, but also produce improvement strategies that are internally generated, which will ensure that they are feasible within current resources.[21] Protocols or work instructions may serve as additional sources of information on work-as-imagined. Depending on local procedures in the hospital, in-person interviews with staff can be informal or conducted by a formal investigation committee. Because Safety-II research primarily focuses on everyday practice, these interviews could also be conducted with colleagues who are acquainted with the work process, but not directly involved in the sentinel event. In this manner, interviews may be less affected by feelings of shame, guilt and self-blame, and directly involved providers can receive peer support. Potentially, this may reduce or eliminate the need for interviews with the directly involved professionals, and hence the negative emotional consequences that these investigation interviews can have for them.

Visualization of the scenario

Once insight into the everyday work process has been obtained, the specific event can be investigated as a scenario within that generic process. A method to visualize work processes is the 'Functional Resonance Analysis Method' (FRAM), developed by Hollnagel, who also developed the Safety-II theory. A FRAM model depicts all activities and their (inter)dependencies within a work process and can be developed on the basis of data collected through various methods such as interviews, document review or observations.[22] These models can be used to study how a process functions in everyday practice,[20] but also to evaluate changes to these processes in advance,[23] or to study incidents in relation to the everyday process.[24] FRAM is increasingly used in healthcare,[20,23,24] but has been more commonly applied in other settings, such as aviation or air traffic management.[25,26]

Next steps

Local clinical leadership and researchers involved in sentinel event investigations could use Just Culture and Safety-II principles to shape accountability and investigations differently, by asking different questions in the aftermath of these events (Table 1). This approach supports

a climate of psychological safety that facilitates learning by actively shifting the focus from individual culpability to collective recovery. It furthermore addresses the needs of involved staff members, who share the need that the institution and its professionals learn from the situation with patients and families. Subsequently, an in-depth investigation with a Safety-II approach will focus not only on the specific event, but also seeks to understand how the underlying process in everyday practice usually goes right, which can be used as the basis for explaining how the event could have happened. This adds more nuances and a sense of practical reality to the investigation, yielding lessons that are closely aligned with the 'messy reality' of everyday practice.

Future research is warranted to study the benefits of this approach to sentinel event investigations, including effects on patients and staff (e.g. feelings of psychological safety), and the subsequent learning process. These studies should examine whether, for example, interviews with colleagues instead of directly involved professionals provide sufficient information for the investigation, and whether the involved professionals indeed suffer less emotional damage when they are no longer asked to recount the event in interviews.

Both Just Culture and Safety-II provide valuable principles that can be applied to improve how we learn from sentinel events, and how we deal with those involved, so that the professionals will soon be able to provide safe and high-quality care to patients in the future.

REFERENCES

1. Dekker SW, Hugh TB. A just culture after Mid Staffordshire. *BMJ Qual Saf*. 2014;23(5):356-358. doi:10.1136/bmjqs-2013-002483.
2. Heijboer L, Heuver G, Schilp J, Wagner C. 'Just Culture': inzicht in calamiteitenbeleid in Nederlandse zorginstellingen (Dutch). *KiZ*. 2015;25:24-27.
3. Frankel A, Haraden C, Federico F, Lenoci-Edwards J. *A Framework for Safe, Reliable, and Effective Care. White Paper.* Cambridge, MA; 2017.
4. Braithwaite J, Wears RL, Hollnagel E. Resilient health care: Turning patient safety on its head. *Int J Qual Heal Care*. 2015;27(5):418-420. doi:10.1093/intqhc/mzv063.
5. Dekker S. *Just Culture: Restoring Trust and Accountability in Your Organization*. Taylor & Francis Ltd; 2016.
6. Santomauro CM, Kalkman CJ, Dekker SWA. Second victims , organizational resilience and the role of hospital administration. 2014;3(5):95-103. doi:10.5430/jha.v3n5p95.
7. Dekker SWA. *Second Victim: Error, Guilt, Trauma and Resilience.* Boca Raton, FL: CRC Press/Taylor & Francis; 2013.
8. Wu AW, Lipshutz AK, Pronovost PJ. Effectiveness and efficiency of root cause analysis in medicine. *Jama*. 2008;299(6):685-687. doi:10.1001/jama.299.6.685\r299/6/685 [pii].
9. Wu A. Medical error: the second victim. The doctor who makes the mistake needs help too. *BMJ*. 2000;320(7237):726-727. doi:10.1136/BMJ.320.7237.726.
10. Edrees H, Connors C, Paine L, Norvell M, Taylor H, Wu AW. Implementing the RISE second victim support programme at the Johns Hopkins Hospital: a case study. *BMJ Open*. 2016;6(9):e011708. doi:10.1136/bmjopen-2016-011708.
11. Friele RD, Sluijs EM. Patient expectations of fair complaint handling in hospitals: empirical data. *BMC Health Serv Res*. 2006;6(106). doi:10.1186/1472-6963-6-106.
12. Gallagher TH. Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors. *Jama*. 2003;289(8):1001. doi:10.1001/jama.289.8.1001.
13. Vincent C, Young M, Philips A. Why do people sue their doctors? A study of patients and relatives taking legal action. *JAMA*. 1994;343:1609-1613.
14. Wu AW, Steckelberg RC. Medical error, incident investigation and the second victim: Doing better but feeling worse? *BMJ Qual Saf*. 2012;21(4):267-270.
15. Scott SD, Hirschinger LE, Cox KR, McCoig M, Brandt J, Hall LW. The natural history of recovery for the healthcare provider "second victim" after adverse patient events. *Qual Saf Heal Care*. 2009;18(5):325-330. doi:10.1136/qshc.2009.032870.
16. Bullen J. Dr Bawa-Garba: Who's to blame when a medical tragedy occurs? ABC news website. http://www.abc.net.au/news/health/2018-02-15/dr-bawa-garba-who-is-to-blame-when-a-medical-tragedy-occurs/9417166. Accessed 6 May 2018.
17. Hollnagel E. *Safety-I and Safety-II. The Past and Future of Safety Management.* (Ashgate Publishing Limited, ed.). Farnham, UK; 2014.
18. Hollnagel E, Wears R, Braithwaite J. *From Safety-I to Safety-II: A White Paper.* Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.; 2015. https://resilienthealthcare.net/wp-content/uploads/2018/05/WhitePaperFinal.pdf (accessed 19 May 2018).
19. Besnard D, Hollnagel E. I want to believe: Some myths about the management of industrial safety. *Cogn Technol Work*. 2014;16(1):13-23. doi:10.1007/s10111-012-0237-4.

20. Damen NL & de Vos MS, Moesker M, Braithwaite J, et al. Preoperative anticoagulation management in everyday clinical practice: an international comparative analysis of work-as-done using the functional resonance analysis method. *J Patient Saf* 2018 Jul 7. doi: 10.1097/PTS.0000000000000515
21. Baxter R, Taylor N, Kellar I, Lawton R. What methods are used to apply positive deviance within healthcare organisations? A systematic review. *BMJ Qual Saf*. 2016;25:190-201. doi:10.1136/bmjqs-2015-004386.
22. Hollnagel E, Hounsgaard J CL. *FRAM – The Functional Resonance Analysis Method – A Handbook for Practical Use of the Method*. Middelfart, Denmark; 2014. http://functionalresonance.com/onewebmedia/FRAM_handbook_web-2.pdf (accessed 19 May 2018).
23. Clay-Williams R, Hounsgaard J, Hollnagel E. Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implement Sci*. 2015;10:125. doi:10.1186/s13012-015-0317-y.
24. Hounsgaard J. Patient safety in everyday work. Learning from what goes right [MSc thesis]. University of Southern Denmark; 2016. http://functionalresonance.com/onewebmedia/Hounsgaard%20(2016).pdf (accessed 19 May 2018).
25. Woltjer R. Functional Modeling of Constraint Management in Aviation Safety and Command and Control [Doctoral thesis]. 2009. http://liu.diva-portal.org/smash/get/diva2:210824/FULLTEXT01.pdf (accessed 22 August 2017).
26. De Carvalho PVR. The use of Functional Resonance Analysis Method (FRAM) in a mid-air collision to understand some characteristics of the air traffic management system resilience. *Reliab Eng Syst Saf*. 2011;96:1482-1498.

Chapter 11

General discussion

GENERAL DISCUSSION

This PhD thesis examined current practices and sources for learning from adverse outcomes that aim to contribute to healthcare improvement, focusing on three approaches (Figure 1):

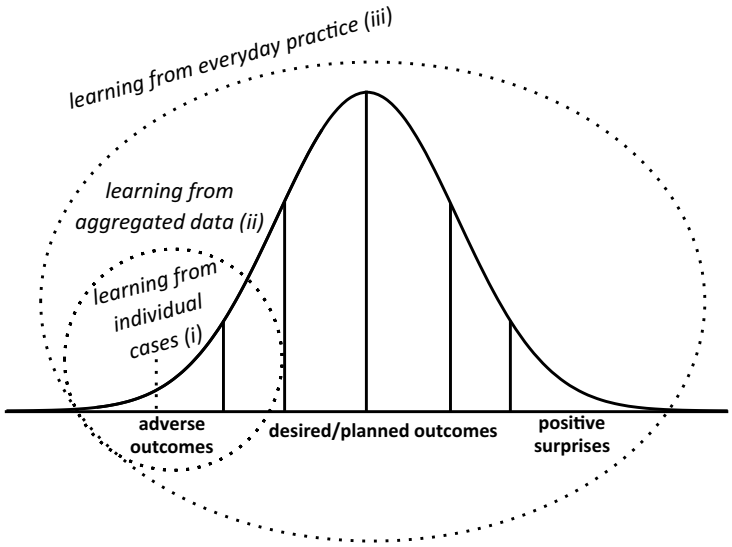
(i) Learning from discussions of individual cases at M&M conferences;

(ii) Learning from adverse outcomes in the context of other information sources, such as incidents, complaints and patient experiences.

(iii) Learning from processes in everyday practice

These approaches for learning are affected by various challenges embedded in healthcare practice and improvement, which will be considered in relation to the results of the research in this thesis and the wider literature. This will not be a comprehensive overview, but a reflection on some of the pertinent challenges and issues that we are facing in this field.

Figure 1. The normal distribution of the outcomes of everyday practice and the different approaches for learning from these outcomes (adapted from figure 1, chapter 1)



The depicted approaches are focused on: i) individual cases with adverse outcomes (e.g. at M&M conferences), ii) aggregated data on adverse outcomes (e.g. incident reports or patient complaints); iii) everyday practice with adverse as well as desired outcomes.

LEARNING FROM CASE EVALUATIONS

Although the M&M conference is the traditional forum for case-based learning, the research presented in this thesis indicates that it does not meet current expectations of serving as a means for continuous and system-wide improvement **(chapters 2-4)**. It is clearly a significant challenge to remain sensitive to the opportunities for learning, to subsequently apply these

lessons in clinical practice, and to then sustain the lessons learned in the collective memory of the department or wider organization. Issues that may particularly hamper the effectiveness of learning from individual case discussions are related to a narrow focus of learning, and challenges posed by cultural factors and the multidisciplinary nature of healthcare.

Persistent focus on individual-based rather than systems-based lessons

It has long been acknowledged that a simplistic focus on 'human error' is not an effective strategy. Nearly twenty years ago, the landmark publication *To Err is Human* declared that "The problem is not bad people; the problem is that the system needs to be made safer".[1] This 'systems approach' has been widely embraced as a more effective approach to achieve sustainable improvement in healthcare.[2,3] However, it seems that these principles have not yet been successfully implemented in practices for learning from adverse outcomes. **Chapter 4** provides empirical evidence that lessons drawn from M&M are often person-based rather than systems-based: lessons often concerned reminders to adhere to protocols or to pay more attention despite the fact that similar issues recurred over time. Others have described a similar focus in root cause analyses in healthcare, where the investigation may identify a deviation from prescribed practice as 'human error' without delving deeper into the underlying drivers of the behavior.[4,5] Often the subsequent corrective actions are limited to education and reinforcement of local policies but do not address the systemic problems that led to the behavior and therefore place others at risk in the future. A focus on correcting individual behavior will also not be effective in preventing 'organizational forgetting',[6] as seen in the case example in Box 1. Although systems-based strategies, such as environment (re-)design or forcing functions, require more effort, they ultimately have greater and longer-lasting effects than person-based lessons.[4]

It has been demonstrated that in everyday clinical practice, obstacles that hinder expected work processes, such as missing resources, greatly outnumber human mistakes (86% vs. 14%).[7] Therefore, in many cases, mere training will not suffice, because it cannot compensate for poor system design.[8] System problems are not only a hazard for patient harm and a source of frustration, but also waste valuable, well-paid professionals' time. It has been estimated that nurses spent about 33 minutes per eight-hour shift (or 15% of the time of 26 nurses) coping with system failures.[7,9] A better strategy would be to evaluate and address the conditions that allowed a problem to occur, famously described as "draining the swamp, not swatting at mosquitoes."[4,10] However, it seems that our initial responses to cases discussed at M&M or to complaints received from patients (**chapter 6**), are often regarded as end products rather than the beginning of a longer process of investigation, implementation, follow-up and adaptation. Such an approach only scratches the surface of the system, failing to dig deeper into underlying issues. In medical terms, we are often still treating symptoms rather than diagnosing and curing the disease when it comes to learning and improvement.

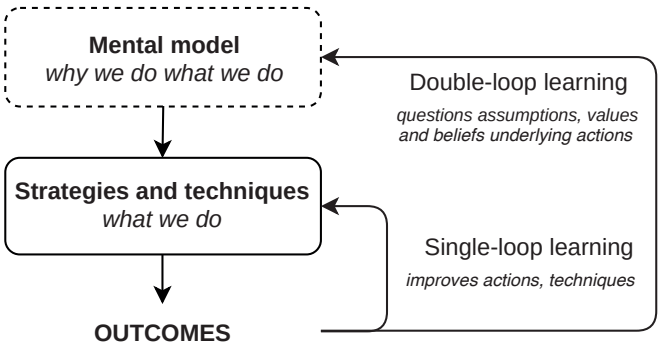
Box 1. Real case example of 'organizational forgetting'

In a large acute care hospital, the wrong lens was inserted during an elective eye surgery led by an experienced eye surgeon. The error was detected and the patient was safely reoperated. A subsequent root cause analysis of the case identified that there had been two lenses in the operating room: the surgeon had brought the correct lens, but a wrong lens had been brought in by an operating department assistant. The investigation concluded that the incident had been caused by having more than one lens in the room and a failure in the double-checking process. Plans for improvement included a training program, improved documentation, a protocol emphasizing the responsibility of the surgeon to select the appropriate lens, and a poster emphasizing the importance of double-checking. One year later, a different patient with a different surgeon had the same procedure in the same hospital. Once again, the wrong lens was implanted. In this case, the staff member who chose the wrong lens was the surgeon.

Example modified from Peerally et al. BMJ Qual Saf 2017;26:417-422

In the organizational learning literature, the distinction between fixing the problem at hand versus actually understanding and addressing underlying conditions is referred to as 'first-order vs. second-order problem solving' or 'single-loop vs. double-loop learning'.[7,11,12] Single-loop learning seeks to find an explanation for an outcome (i.e. what did we do to get this result), which focuses on "making techniques more efficient."[13] This corresponds to the observed focus of learning at M&M in **chapter 4**. Double-loop learning is more reflective and questioning, confronting basic assumptions and values by asking why we do what we do (Figure 2).[12,14] This way, individuals are encouraged to reflect on the 'mental maps' they use to take action, of which few are usually aware.[14] Put differently, single-loop learning is about "doing things right", whereas double-loop learning focuses on "doing the right things". To illustrate, the many recurring lessons in **chapter 4** stipulated that attention and techniques for patient positioning should be improved, whereas an example of second-loop learning would have been to consider why positioning may have been given lower priority in these cases (e.g. unclear task division or trade-offs across goals), and how this should be balanced in future cases. The scientists who developed the theory of double-loop learning assert that this is an important mechanism to support professionals in making informed decisions in rapidly changing, often uncertain contexts,[11,14,15] such as in healthcare.

Figure 2. Single-loop learning and double-loop learning



Effects of culture and psychological safety

While most research on M&M has focused on organizational aspects (e.g. presentation formats, moderators), learning and change theories underline that these processes are also affected by psychological and cultural factors. How culture may hamper learning, e.g. by focusing on blame, is discussed by the 'Just Culture' theory central to **chapter 10.** It is clear that more work is required to establish such a culture, as illustrated by the results of the study in **chapter 2**. Although most respondents expected that M&M should be free of shame and blame, 3 out of 10 respondents at both sites reported that this was their experience only sometimes or rarely in practice.

The findings of the studies in **chapters 3 and 4** indicate that it requires more than just organizational efforts, such as how the meeting is set up, to promote a learning environment with open discussions. This is captured in the renowned quote "culture eats strategy for breakfast", which has been attributed to management expert Peter Drücker. Based on interviews with clinicians, feelings of ownership and control (or: 'motivation' and 'realization') were identified as factors of influence on learning at M&M. The qualitative study in **chapter 3,** unique in the field of M&M research, reveals how audience composition and team dynamics additionally affect discussions at M&M. Certain unwritten rules exist that may be potential barriers to speaking up, such as the high value placed on 'team spirit' and the subsequent unwillingness to be perceived as 'back-stabbing'.

The organizational learning literature highlights how 'psychological safety' is essential to fostering a learning environment, described as one in which people feel comfortable with speaking up with questions, observations, insights and concerns, even if those are perhaps difficult or perceived as bad news.[9] The construct of psychological safety describes an individual's "perceptions of the consequences of taking interpersonal risks,"[16] such as acknowledging lack of competence, asking for help or trying something new. Psychological safety is a critical factor in understanding phenomena such as voice, teamwork, team learning and dealing with uncertainty.[16] The relationship between psychological safety and learning is evident: if people feel safe to voice concerns, admit mistakes, offer suggestions or provide feedback, they will be more likely to do so. Psychological safety also affects everyday performance: perceived consequences of taking risks will determine how one will respond to situations with uncertainty, or a need for creativity, assistance or collaboration – all of which are common in healthcare.

A psychologically safe environment is not created from the top down but from the bottom up, and thus greatly dependent on the behavior of *local* leadership.[9] A critical aspect is that leaders need to be clear about what constitutes unacceptable behavior, which is where the literature on 'psychological safety' overlaps with that on 'Just Culture' (**chapter 10**). Since learning in teams involves personal effort, this process must be inspired, organized, supported and led by frontline leaders.[9] This aligns with **chapter 3** that describes how 'motivation' and 'realization' serve as mediating pathways for successful M&M, as well as with the findings

of **chapters 2 and 3** that point to the important role of strong leadership (e.g. moderator, dedicated committee).

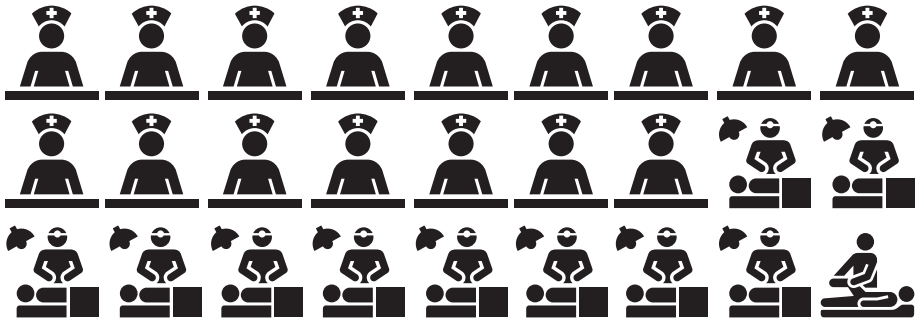
The influence of culture has also been discussed in relation to what seems to be the best example of a successful large-scale patient safety intervention: the Michigan Keystone project to decrease catheter-related bloodstream infections.[17] Experts attribute the project's success to the fact that it not only included technical interventions, such as a checklist, but was also designed to improve culture, teamwork and communication.[18–22] Checklists were just one component in a wider program that influenced the culture of the teams (e.g., shifting power relations, empowering nurses).[18] Moreover, local teams customized the checklist to fit their specific context. When another group implemented this program without the socioadaptive components, improvements slowed down until these were added.[23] In essence, this project abandoned a 'command and control' regime, where instructions (e.g., checklists) are simply dictated to professionals, instead creating "social networks with a shared sense of mission".[18] While instructions may seem effective in theory, professionals will seek workarounds in practice if they do not believe in their value. To illustrate this, that a similar project in England was less successful and this was partially attributed to a misalignment of the goals, interests and priorities with those of staff at the sharp-end.[21] Again, culture may "eat strategy for breakfast."

Challenges posed by multidisciplinarity

Although healthcare professionals have a high turnover rate, particularly in teaching hospitals, underlying system conditions are likely to affect new employees who start to work in that environment. This also explains why systems-based improvements are more effective than person-based improvements. Moreover, as found in **chapters 3 and 4**, a lack of continuity of clinicians (e.g., rotating residents) can make it particularly difficult to implement and sustain lessons that are focused on people rather than environments. For example, it has been estimated that a mean total of 26.6 (range 2-75) healthcare professionals are involved in a surgical patient's stay (Figure 3).[24] These numbers reaffirm that it is unrealistic to attribute negative patient experiences or complaints to individual providers (**chapter 6**).

The presented research also illustrated that the multidisciplinary nature of healthcare plays a role in learning and implementation processes: lessons that involved other disciplines were infrequent overall, but recurred frequently over time (**chapter 4**). Although many studies, including **chapter 4**, propose multidisciplinary participation as a way forward for M&M,[25–28] the qualitative study in **chapter 3** adds nuance to these studies by showing that participants may feel inhibited to speak freely when other disciplines or specialties attend the conference. Yet, it would be unrealistic to try to improve a process in isolation from others involved, since many problems have their origin in other parts of the system.[7] This was also illustrated by the workflow interruptions in **chapter 8** that seemed to stem from problems encountered by other providers, such as nurses, creating the need to communicate via text paging. Similarly, the models in **chapter 9** revealed how activities of multiple disciplines and specialties are tightly

Figure 3. Average number of healthcare professionals involved in a surgical inpatient's stay (i.e. 15.9 nurses, 10.0 doctors, 0.8 allied health professionals).



Estimates based on: Whitt et al. N Z Med J 2007;120(1253):1-8.

coupled, which helped to understand (and show providers during reflection meetings) how a problem early on in the process might propagate through the system, affecting the activities of other team members. Overall, it seems that, although modern healthcare is increasingly multidisciplinary, our practices for learning and improvement lag behind in readiness to cross traditional boundaries between departments and disciplines.

LEARNING FROM AGGREGATED DATA

Over the years, hospitals have implemented various systems to collect data, reflecting the quality, safety and patient experience of the delivered care (Table 1). Previous studies have examined various data sources and revealed that each collect different types of information, supporting hospitals' use of various methods to detect safety issues and targets for improvement.[29–33] The research in this thesis (**chapters 5-7**), however, adds that although each system collects different signals from the same patient journey, these data have complex relations at the patient level. Therefore, a specific opportunity that is yet to be seized is making better use of available data sources in relation to each other.

The need to connect the silos of information

There is not only a practical objective to make effective use of the collected data to improve care, but it would also be unethical to ask patients and providers to report information if this is not used to its full potential. **Chapter 5** illustrates how data triangulation can reveal complex relations between events that would remain obscured when these data are used in isolation. Individually, these data only allow for uni-directional assessments (i.e., incident → adverse event[AE]) of one-on-one relations between events; namely, whether an incident caused AEs (incident reporting) or whether AEs were preceded by suboptimal care (record review). At the admission-level, these data may have many-to-many relationships, potentially in the opposite direction when initial AEs trigger incidents due to increased complexity or vulnerability.

Table 1. Features of hospital data sources for learning and improvement studied in this thesis.

Source	*Features*[1]	*Source*	*Features*[1]
n=total per year for one department		*n=total per year for one department*	
 **Admission data (EHR)**	- Automatically collected - Contains patient identifiers and patient characteristics - Numerator for other sources	 **Patient complaints**	- 'Stories' from patients - Reveals issues often not captured elsewhere - Difficult to use aggregated form: unstructured data of low and unreliable volume
n=3678 (100%) pts		*n=9 (for inpatients)*	
 **Adverse event registry**	- Collected by providers (underreporting risk) or record review (labour intensive) - Useful for benchmarking and to inform patients on risks	 **Patient experience surveys**	- Voluntary reports of patients - Combination of open text and validated survey items - Affected by response bias - Can be used for monitoring
n=759 / 647 (18%) pts		*n=921*	
 **Lessons from M&M conferences**	- Documented by providers - Useful for tracking progress and M&M output, e.g. using recurrence of lessons	 **Provider communication data**	- Text pages ca. 193.000/year, but not used by all hospitals - Useful to study frequency, content and distribution of interprovider communication
n=38		*differs per source*	
 **Incident reporting system**	- 'Stories' from providers - Cannot be used for monitoring (unreliable reporting rates) - Unique in revealing hazards before harm is inflicted		
n=552 / 339 (9%) pts			

Pts, inpatient admissions.

[1]Admission, adverse event, incident, patient complaints and experience survey numbers represent total numbers from the LUMC surgical department in 2015 (chapter 7). Number of M&M lessons and text paging volume represent mean annual total from chapters 3 and 8.

Similarly, **chapter 7** shows how linkage of safety and patient experience data allows a more comprehensive approach to make sense of this information for improvement. Although adverse outcomes were not independently associated with risk of a suboptimal experience, they did increase this risk when patients also reported problems with 'respect' and 'continuity and transition' (interaction effect). Patient experience data, however, are typically presented in aggregated, provider-level reports, and data linkage is complicated by surveys being anonymous.[34] Even though regulatory and ethical standards control anonymity of patient surveys,[34] patients themselves may be willing to participate in this sort of data linkage,[35] especially when checks and balances are in place (e.g. a trusted third party to link and then anonymize the

data). Complaints data represent another source of information from the patient perspective, but these also typically remain isolated from improvement or clinical staff, as highlighted in **chapter 6**. In addition, while not commonly used for this purpose, hospital communication data, such as text paging data, can be used to examine bottlenecks in care processes, but the large volume of these free text data requires more specific techniques to analyze this wealth of information (**chapter 8**).

Cultural factors affecting data collection

A paradox is present in the relation between local culture and reporting data: the less psychologically safe, blame-free and 'just' the culture of a department, the better their metrics will seem because reporting will be discouraged. Even in departments with a blame-free and safe environment, important events may go unreported as clinicians have a tendency to fix problems on the spot, without tracking them to their source or informing others involved either in the department or across the hospital.[7,36,37] Although high levels of reporting may suggest a strong culture of reporting and thus safety, this could also reflect a poor culture of learning that resulted in repeated reports of the same type[38] – akin to the recurring lessons in **chapter 4**. Another difficult aspect of reporting systems is that they may be misused as a means to delegate the problem to others or to avoid difficult conversations with colleagues. While not discussed in the study itself, many of the incident reports examined in **chapter 5** reflected frustrations with colleagues that did not seem to have a place in incident reporting systems (e.g., "physician did not listen or respond to my concerns as a nurse"). Another example was observed during a team meeting in which a physician ordered a nurse to file an incident report on another nurse who had made more than three unsuccessful attempts to draw blood from a patient. The physician stated that "this is not the way we do things around here" and chose to turn to the incident reporting system instead of talking to the nurse or team about this issue.

Safety bureaucracy

The current state of the patient safety field has been described as a one of 'confusing complexity,'[39,40] referring to the theory that knowledge moves in three phases (i.e. superficial simplicity → confusing complexity → profound simplicity).[41] 'Superficial simplicity' is reflected in the initial notion that specific methods, such as incident reporting, could simply be adapted from other safety-critical industries.[38,39] It has become increasingly clear, however, that fundamental aspects of these methods were misunderstood, misapplied or left out,[38] and safety issues in healthcare appeared to be far more complex and omnipresent than initially expected.[39] The report that describes the 'confusing complexity' in patient safety argues that this is illustrated by the large variety of specific improvement targets with interventions for each, such as surgery checklists, infection prevention programs, and barcoding.[39] In light of the research in this thesis (**chapters 5-7**), one may argue that the wealth of information produced by the separate data collection systems also adds to this 'confusing complexity'.

Now that methods are in place and staff have been encouraged to report all potentially relevant information, it has become a challenge to process and prioritize all this data. Incident reporting alone can generate more than 5000 reports per hospital per year.[42,43] As a result, important signals in this data may be swamped with noise, and analytical and attentional resources may be overburdened.[38,42,44,45] In itself, quality and safety management generates additional work and bureaucratic means.[46] A recent study, part of a national initiative to reduce the overall administrative burden for clinicians, revealed that Dutch medical specialists spend an average of 15 hours per week on administrative tasks.[47] Another study estimated that residents spend an average 38% of their 10-hour workdays on administrative tasks, and an additional 51 minutes from home.[48] This raises the question of whether administrative tasks related to quality and safety management, such as reporting systems or administration for M&M, further contribute to the overall burden of administrative work for unclear or potentially limited gains. In any case, the study in **chapter 2** indicates that clinicians do not perceive adequate gains from M&M, as it does not meet their expectations for improvement and changes in clinical practice.

LEARNING FROM EVERYDAY PRACTICE

By design, current practices for learning have a focus on reacting to events where there is a lack of safety (e.g., incidents, complaints, case reviews) and pay little attnetion to how the system usually works and performs. As a result, many of these practices are focused on individual cases and the solutions are likewise aimed at preventing specific, and often rare, failures.[6] However, even the aggregated data discussed above only represent a small subset of outcomes of everyday practice, namely, only the adverse ones, and therefore provide little information on how 'safety' is achieved and ensured. An analogy would be to study how a successful marriage is built and maintained, but only including divorced couples as study subjects. A more proactive proactive approach to safety, labelled Safety-II, focuses on how work succeeds in everyday practice and how to enhance this successful performance of the system.

Understanding work-as-done in everyday practice

Healthcare can be characterized as a complex adaptive, socio-technical system, in which human activities and technology are tightly coupled. One of the features of complex dynamic systems is that accidents are often preceded by *normal work*, which may contain the daily frustrations, improvisations and workarounds that are 'everyday circumstances' for professionals.[46,49,50] As a result, these circumstances do not typically exceed the threshold of a problem worthy of reporting for clinicians, and hence do not surface in the team discussions or reporting systems described above. Yet, these are e

"precisely the kinds of things that do show up in big accidents."[46] In many cases, outcomes of complex systems are *emergent* rather than resultant, because variability may combine in unexpected ways, producing disproportionate, non-linear effects (i.e., more than just the sum

of the parts).[51,52] This explains why properties of complex systems cannot be directly predicted from its elements.

Although a single, simple or one-size solution does not exist for problems in complex systems with multiple interdependent elements, these elements can potentially be reshaped to increase likelihood of success.[53] **Chapter 9** presents how the Functional Resonance Analysis Method (FRAM) can be used to increase understanding of a process in everyday practice. A central idea in the underlying theory is that understanding of the everyday functioning of a complex system provides a more useful basis for understanding a specific development within that system, such as a sentinel event.[51,54,55] However, the ability to support things to go right in everyday practice requires an understanding of how things are actually done in practice, not just 'in theory', as well as an understanding of the underlying conditions. Simply reminding clinicians to adhere to the 'paper version' of local policies (i.e. single-loop learning) will not solve underlying problems such as impracticalities or conflicting expectations in these policies (i.e. double-loop learning). For case investigations, this approach would add a different type of questions than we normally use, to provide insight into the context of clinicians' work, such as: Why did professionals believe they were doing the right thing considering the circumstances? Why did it seem acceptable and make sense at the time? Were there any trade-offs involved, for example, in attention allocation or between efficiency and thoroughness, and are these common?[12,56]

Lack of compliance could be viewed as a gap between work-as-imagined and work-as-done, and bridging this gap requires understanding *both sides*.[57,58] Clinicians rarely intentionally violate policies and likely have various reasons for doing something in a certain way.[6] Broader consideration of the rest of the system and the 'messy reality' of clinical practice, provides valuable insights into, for example, the underlying reasons for workarounds by clinicians.[6,59] **Chapter 9** demonstrated how work-as-done may deviate from what could be expected based on guidelines or policies (work-as-imagined), and points at pragmatic reasons that may explain this. These findings may have been interpreted as 'protocol deviations' that produce adverse outcomes if identified in a sentinel event investigation, while they appear to be part of the everyday work that commonly produces desired outcomes.

Ultimately, plans for improvement need to help to make the right thing to do, the easy thing to do for those at the frontline.[4] In practice, this may not yet be the case and there remains an ongoing reliance on clinicians' flexibility and compensatory mechanisms. This was illustrated by a Danish study filming nurses at work during regular medication dispensation, revealing that nurses had to compensate for inconsistencies between the lay-out of the prescription software and the medication tray.[60] Moreover, both the software and tray had little relation to the physical layout of the patient beds in the rooms, which nurses used as a 'mental picture' of reference while dispensing medications for these patients. This serves as a good example of how everyday practice with successful rather than adverse outcomes, can serve as a meaningful study object to enhance safe performance. A large advantage of this proactive approach

to safety is that it does not require a harmful or negative event, and thus does not require interviews with potentially traumatized patients and providers (**chapter 10**).

Actions are not a priori acceptable or unacceptable

A focus on the wider system does not mean to imply that clinicians are not responsible for their actions, but honors the notion that their actions are affected by the context in which they occur.[2] While the Just Culture philosophy is sometimes misused a means to determine the culpability of 'unsafe acts' (e.g., with a flow chart), this philosophy actually underlines that professionals' actions cannot be viewed as a priori 'acceptable' or 'unacceptable', but that this greatly depends on the context (**chapter 10**).[6,61,62] The systems approach should neither be misunderstood as attempts to reduce professionals' autonomy through, for example, standardization, or to seek explanations for failure outside of individuals, simply blaming the system.[2] In contrast, it strives to design the system in such a way that it supports individual autonomy and competence in creating desired outcomes.[2] Because procedures, protocols and checklists do not guarantee success or safety in itself, professionals' autonomy and resilience are key factors for success in practice.[2,54]

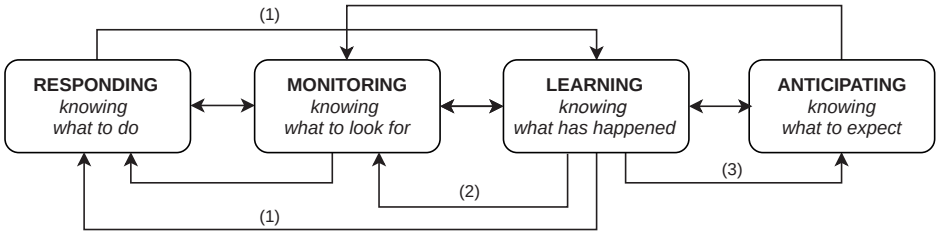
Resilient performance

To a great extent, hospitals rely on dedicated and adaptable clinicians to compensate for problems and to cope with uncertainty and complexity in everyday practice. This resilience allows achieving success despite conditions that could easily lead to failure (e.g. unusual demands, disruptions, goal conflicts, inaccurate or incomplete information), and allows quick recovery after failure.[63] This is why we should refrain from seeing humans as merely a hazard in (e.g. of error) our systems but instead appreciate their essential role in enabling success under varying circumstances. In other words, "People are solutions, not problems."[64] The field of resilience engineering focuses on enhancing 'resilient performance', defined as *the ability to sustain required operations under both expected and unexpected conditions by adjusting functioning prior to, during, or following events (changes, disturbances and opportunities)*.[65] Although often unnoticed, safe and high-quality care regularly depends on resilience (e.g. responding to a high influx of patients).[63] Lack of insight can easily lead to misjudging contributors to resilience as 'waste' and eliminating them (e.g. slack resources that improve reliability and agility).[63] Therefore, it is a critical need for patient safety to find ways to identify and enhance resilience.[63] Resilience engineering proposes four abilities necessary for resilient performance[65] (Figure 4):

- *the ability to respond* to (ir)regular changes, disturbances and opportunities;
- *the ability to monitor* components that could seriously affect system's performance;
- *the ability to learn* from experience (representative events, not only catastrophes);
- *the ability to anticipate* potential disruptions, demands, constraints or conditions.

The ability to learn from experience is central to this thesis, with an additional focus on monitoring in the studies on aggregated data (**chapters 5-8**). More specifically, **chapters 5 and 7** discuss how triangulation of available data can be used to assess the ability to respond, by examining how further problems, such as other AEs/incidents or a negative patient experience, were prevented in cases with initial AEs. **Chapter 9** illustrates how FRAM can be used to examine the current state of the system, including essential functions, interdependencies and variability (ability to monitor). FRAM can also be used to study something that has happened (ability to learn),[12] or to assess potential problems with implementation of a new protocol or process design (ability to anticipate).[66]

Figure 4. Potentials for resilient performance.



Adapted from Hollnagel (2015).[65]
(1) Learning from previous responses may improve our ability to respond in future cases;
(2) Lessons learned may affect our monitoring strategies;
(3) Lessons learned may inform us about what to expect and anticipate.

PRACTICAL IMPLICATIONS AND FUTURE PERSPECTIVES

Despite the increased attention and information on patient safety, research indicates that widespread improvements have not occurred.[67–69] One potential implication from the above discussions is that this may be due to the mismatch between the interventions we use and the real nature of the system to which they are applied. The challenge is therefore about how to successfully shift the focus from person-based, technical solutions towards greater appreciation for the system, its complex-adaptive nature, cultural factors, and the crucial role of humans to ensure success under varying circumstances.

Reflective discussions

Team meetings for learning and improvement (e.g. M&M) need to be more reflective and contemplative, striving to achieve double-loop rather than only single-loop learning. In this respect, focusing discussions on the underlying processes in everyday practice rather than specific cases may help to bring discussions to a higher level. Feedback to staff on progress and effects of formulated plans needs to improve greatly to encourage a longer process of investigation, implementation and follow-up (e.g. using rapid-cycle improvement strategies). Additional time for follow-up and feedback may mean that fewer cases can be investigated

within the available time, but a more thorough approach will be more meaningful than superficially studying large volumes of data.[70] Although multidisciplinary participation may negatively affect openness, it is important to plan (additional) meetings with "the whole system in the room" (a concept from 'appreciative inquiry'[71]) to gather information and create engagement for change. Schools and training programs for physicians and nurses play an important role in harnessing an open, cooperative culture among professionals from diverse disciplines and specialties; yet, it is just as important that senior clinicians reinforce and model these behaviors.

Combining existing and novel resources and methods

Currently available data in hospitals (Table 1) should be linked to allow triangulation between information sources and more comprehensive analyses. Furthermore, these data can be integrated into current practices, for example, by discussing AEs at M&M in the context of patients' experience and incidents. Linkage of admission data to the various sources of quality and safety data would allow identifying cases *without* adverse outcomes, perhaps despite challenging circumstances (e.g., high-risk patient profile or procedure), which can be targeted for further study to understand how safety was achieved (e.g., resilience). Future research should explore how to reduce the overall burden of data collection and administration, while still being informed about quality and safety of care in a way that we can report to others (e.g., board of directors, inspectorate). Traditional methods should be combined with complex systems approaches to safety. For example, the commonly used 'lean' method can be used to identify potential resources of waste, after which FRAM can be employed to study which resources are required to manage unexpected variability, referred to as 'slack resources'.[72] Another example is that statistical process control can be used in combination with FRAM models to measure relevant outputs of functions.[73]

Culture and team dynamics

For many aspects of clinical practice, we need more than technical solutions if we are to achieve safer care, as these cannot solve problems that are primarily social and cultural.[18] The described difficulties with multidisciplinary discussions touch upon a more deep-rooted problem in healthcare, namely the barriers that exist between medical disciplines and specialties, which is a promising avenue for further study in relation to (effects on) patient safety. Many studies in patient safety, however, focus on clinical rather than cultural interventions, resulting in a paucity of evidence on how to achieve, for example, better teamwork.[22] There is thus a great need for more research on team dynamics, culture, and resilience in healthcare. A specific challenge for research on these phenomena is that they are not easily converted to numbers.[63] More qualitative (e.g. interviews, direct observation,[74] video ethnography) and mixed-methods designs are thus required, including funding for such 'non-traditional' studies in medicine. Although the science behind patient safety and improvement are not tra-

ditionally part of medicine, they have become integral components of good medical practice and required competencies for clinicians. Moreover, it is important that those who examine and work to improve a process are familiar with it in practice.[46] Yet, there remains a need for experts from other fields (e.g. safety science, human factors, organizational change),[8] and we should call upon their expertise, as we commonly do with epidemiologists or statisticians.

Resilience and system complexity

Patient safety is on the verge of moving from a focus on human error and linear models, to one that embraces complexity, systems thinking and resilient performance. Complexity science and complex adaptive systems theory offer an alternative theoretical framework.[53,75] In addition to studies that describe or model parts of systems (e.g., using FRAM), further studies with complex systems approaches are needed to examine how to implement improvements in these systems.[76] More research is also warranted to identify resilient performance and how it could be enhanced, so that professionals can be equipped for adequate responses to challenging situations. An increased focus on compliance with protocols may inadvertently lead to risk aversion and a constraint on initiative, thus creating an unpreparedness for situations that do not fit those anticipated by the protocols.[46] Further study should address how an increased focus on safety and efficiency can be balanced with the flexibility and resilience required for success, including how to prevent that plans for increased reliability (e.g. double-checking procedures) create 'organized distractions', unnecessary interruptions and increased workload.

CONCLUSIONS

While healthcare has invested in the foundations to gather and learn from data on adverse outcomes, the research presented in this thesis pointed at various challenges that remain. M&M meetings to learn from individual cases exhibit a tendency to focus on individual behavior and technical performance, and thus may benefit from greater reflectivity that triggers learning with greater appreciation of underlying system-level issues. In addition, cultural factors, such as dynamics in teams and among disciplines, were found to affect learning at M&M, which underlines the need for more qualitative research on these domains. Currently available aggregated data remain encased in separate silos, but should be used in closer connection to each other to allow more comprehensive analyses. Proactive and complex systems approaches to safety are promising to further enhance understanding of how everyday practice usually goes right and to support this capacity so that patients' safety can be ensured.

REFERENCES

1. Kohn LT, Corrigan JM, Donaldson M. *To Err Is Human: Building a Safer Health System*. Washington DC, USA: National Academy Press; 1999.
2. Dekker SWA, Leveson NG. The systems approach to medicine: controversy and misconceptions. *BMJ Qual Saf*. 2015;24:7-9.
3. Wachter R, Shojania K. *Internal Bleeding*. New York, NY: Rugged Land; 2004.
4. Trbovich P, Shojania KG. Root-cause analysis: swatting at mosquitoes versus draining the swamp. *BMJ Qual Saf*. 2017;26:350-353.
5. Kellogg KM, Hettinger Z, Shah M, et al. Our current approach to root cause analysis: is it contributing to our failure to improve patient safety? *BMJ Qual Saf*. 2017;26:381-3787. doi: 10.1136/bmjqs-2016-005991
6. Peerally MF, Carr S, Waring J, et al. The problem with root cause analysis. *BMJ Qual Saf Saf*. 2017;26:417-422. doi:10.1136/bmjqs-2016-005511
7. Tucker AL, Edmondson AC, Hall M, et al. Why hospitals don't learn from failures: *Calif Manag Rev*. 2003;45:55-72.
8. Russ AL, Fairbanks RJ, Karsh B-T, et al. The science of human factors: separating fact from fiction. *BMJ Qual Saf*. 2013;22:802-808. doi:10.1136/bmjqs-2012-001450
9. Edmondson AC. Learning from failure in health care: frequent opportunities, pervasive barriers. *Qual Saf Heal Care*. 2004;13:ii3-ii9.
10. Reason J. Human error: models and management. *BMJ*. 2000;320:768-770.
11. Argyris C, Shön D. *Organizational Learning: A Theory of Action Perspective*. Reading, MA, USA: Addison-Wesley Publishing Company; 1978.
12. Hounsgaard J. Patient safety in everyday work. Learning from what goes right [MSc thesis]. University of Southern Denmark; 2016. http://functionalresonance.com/onewebmedia/Hounsgaard%20(2016).pdf (Accessed 20 April 2018).
13. Usher R, Bryant I. *Adult Education as Theory, Practice and Research*. London, UK: Routledge; 1989.
14. Argyris C, Shön D. *Theory in Practice: Increasing Professional Effectiveness*. San Francisco: Jossey Bass; 1974.
15. Argyris C. *Overcoming Organizational Defenses: Facilitating Organizational Learning*. Boston: Allyn and Bacon; 1990.
16. Edmondson AC, Lei Z. Psychological Safety: The History, Renaissance, and Future of an Interpersonal Construct. *Annu Rev Organ Psychol Organ Behav*. 2014;1:23-43.
17. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med*. 2006;355:2725–2732.
18. Bosk CL, Dixon-Woods M, Goeschel CA, Pronovost PJ. Reality check for checklists. *Lancet*. 2009;374:444-445.
19. Shojania KG, Dixon-Woods M. "Bad apples": time to redefine as a type of systems problem? *BMJ Qual Saf*. 2013;22:528-531. doi: 10.1136/bmjqs-2013-002138
20. Pronovost PJ, Cleeman JI, Wright D, et al. Fifteen years after *To Err is Human* : a success story to learn from. *BMJ Qual Saf*. 2016;25:396-399. doi: 10.1136/bmjqs-2015-004720
21. Dixon-Woods M, Leslie M, Tarrant C, et al. Explaining Matching Michigan: an ethnographic study of a patient safety program. *Implement Sci*. 2013;8:70. doi: 10.1186/1748-5908-8-70
22. Shojania KG, Thomas EJ. Trends in adverse events over time: why are we not improving? *BMJ Qual Saf*. 2013;22:273-277. doi:10.1136/bmjqs-2013-001935

23. Palomar M, Álvarez-Lerma F, Riera A, et al. Impact of a national multimodal intervention to prevent catheter-related bloodstream infection in the ICU: the Spanish experience. *Crit Care Med*. 2013;41:2364–72.
24. Whitt N, Harvey R, McLeod G, Child C. How many health professionals does a patient see during an average hospital stay? *NZ Med J*. 2007;120:1-8. http://www.nzma.org.nz/__data/assets/pdf_file/0006/17835/Vol-120-No-1253-04-May-2007.pdf (Accessed 20 April 2018).
25. Kwok ESH, Calder LA, Barlow-Krelina E, et al. Implementation of a structured hospital-wide morbidity and mortality rounds model. *BMJ Qual Saf*. 2017;26:439-448. doi:10.1136/bmjqs-2016-005459
26. Kauffmann RM, Landman MP, Shelton J, et al. The Use of a Multidisciplinary Morbidity and Mortality Conference to Incorporate ACGME General Competencies. *J Surg Educ*. 2011;68:303-308.
27. Deis JN, Smith KM, Warren MD, et al. Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement. Agency for Healthcare Research and Quality (US); 2008.
28. Bal G, Sellier E, Tchouda SD, François P. Improving quality of care and patient safety through morbidity and mortality conferences. *J Healthc Qual*. 2014;36:29-36.
29. Levtzion-Korach O, Frankel A, Alcalai H, et al. Integrating Incident Data from Five Reporting Systems to Assess Patient Safety: Making Sense of the Elephant. *Jt Comm J Qual Patient Saf*. 2010;36:402-410.
30. Sari A, Sheldon T, Cracknell A, Turnbull A. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *Br Med J*. 2007;334:79.
31. Olsen S, Neale G, Schwab K, et al. Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place. *Qual Saf Heal Care*. 2007;16(1):40-44.
32. Christiaans-Dingelhoff I, Smits M, Zwaan L, et al. To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports? *BMC Health Serv Res*. 2011;11:49.
33. de Feijter JM, de Grave WS, Muijtjens AM, et al. A comprehensive overview of medical error in hospitals using incident-reporting systems, patient complaints and chart review of inpatient deaths. *PLoS One*. 2012;7:e31125.
34. Flott KM, Graham C, Darzi A, et al. Can we use patient-reported feedback to drive change? The challenges of using patient-reported feedback and how they might be addressed. *BMJ Qual Saf*. 2017;26:502-507.
35. Ashley L, Jones H, Thomas J, et al. Integrating patient reported outcomes with clinical cancer registry data: A feasibility study of the electronic patient-reported outcomes from cancer survivors (ePOCS) system. *J Med Internet Res*. 2013;15:1-19.
36. Hewitt TA, Chreim S. Fix and forget or fix and report: a qualitative study of tensions at the front line of incident reporting. *BMJ Qual Saf*. 2015;24:303-310. doi: 10.1136/bmjqs-2014-003279
37. Jeffs L, Berta W, Lingard L, et al. Learning from near misses: from quick fixes to closing off the Swiss-cheese holes. *BMJ Qual Saf*. 2012;21:287-294. doi: 10.1136/bmjqs-2011-000256
38. Macrae C. The problem with incident reporting. *BMJ Qual Saf*. 2016;25:71-75. doi:10.1136/bmjqs-2015-004732
39. National Patient Safety Foundation. Free From Harm: Accelerating Patient Safety Improvement Fifteen Years After "To Err Is Human." Boston, MA, USA: National Patient Safety Foundation; 2015.
40. Gandhi TK, Berwick DM, Shojania KG. Patient safety at the crossroads. *JAMA*. 2016;315:1829-1830. doi:10.1001/jama.2016.1759
41. Schutz W. Profound Simplicity: Foundations for a Social Philosophy. Hoboken, NJ: John Wiley & Sons; 1982.

42. Pham JC, Girard T, Pronovost PJ. What to do with healthcare Incident Reporting Systems. *J Public Heal Res*. 2013;2:27.
43. Leiden University Medical Center. *Annual Report*. Leiden, the Netherlands; 2015. https://www.lumc.nl/ove/att/80212012710221/1284574/jaarverslag-2015 (Accessed 20 April 2018).
44. Deeny SR, Steventon A. Making sense of the shadows: priorities for creating a learning healthcare system based on routinely collected data. *BMJ Qual Saf*. 2015;24:505-515. doi:10.1136/bmjqs-2015-003934
45. Macrae C. Early warnings, weak signals and learning from healthcare disasters. *BMJ Qual Saf*. 2014;23:440-445. doi:10.1136/bmjqs-2013-002685
46. Dekker SWA. The bureaucratization of safety. *Saf Sci*. 2014;70:348-357. doi:10.1016/j.ssci.2014.07.015
47. VvAA / FMS. *Administratiedruk Medisch Specialisten: Enquête (Ont)regel de Zorg [Dutch]*. https://www.demedischspecialist.nl/sites/default/files/20171117_DEF%20Rapport-administratiedruk-specialisten.pdf (Accessed 20 April 2018).
48. Schuurman A, Bos S, de Wit K, de Graaf R, Wiersinga W. A day in the life of a medical resident on the ward [Dutch]. *Ned Tijdschr Geneeskd*. 2018;161:D2480.
49. De Carvalho PV, Gomes JO, Huber GJ, Vidal MC. Normal people working in normal organizations with normal equipment: system safety and cognition in a mid-air collision. *Appl Ergon*. 2009;40:325–340.
50. Dekker SWA. *Drift into Failure: From Hunting Broken Components to Understanding Complex Systems*. Farnham, UK: Ashgate Publishing Co, ed..; 2011.
51. Hollnagel E, Hounsgaard J CL. *FRAM – The Functional Resonance Analysis Method – A Handbook for Practical Use of the Method.* Middelfart, Denmark; 2014. http://functionalresonance.com/onewebmedia/FRAM_handbook_web-2.pdf (Accessed 9 February 2017).
52. Hutter MM, Rowell KS, Devaney LA, et al. Identification of Surgical Complications and Deaths: An Assessment of the Traditional Surgical Morbidity and Mortality Conference Compared with the American College of Surgeons-National Surgical Quality Improvement Program. *J Am Coll Surg*. 2006;203:618-624.
53. Rutter H, Savona N, Glonti K, et al. The need for a complex systems model of evidence for public health. *Lancet*. 2017;390:2602-2604. doi: 10.1016/S0140-6736(17)31267-9
54. Hollnagel E, Wears R, Braithwaite J. *From Safety-I to Safety-II: A White Paper.* Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.; 2015. https://resilienthealthcare.net/wp-content/uploads/2018/05/WhitePaperFinal.pdf (Accessed 9 February 2017).
55. Hollnagel E. Before you begin building the model. http://functionalresonance.com/how-to-build-a-fram-model/index.html Published 2016 (Accessed 5 April 2018).
56. Hollnagel E. *The ETTO Principle - Efficiency-Thorougness-Trade-Off: Why Things That Go Right Sometimes Go Wrong.* Farnham, Surrey, UK: Ashgate Publishing; 2009.
57. Shorrock S, Leonhardt J, Licu T, Peters C. *Systems Thinking for Safety: Ten Principles - A White Paper. Moving towards Safety-II.*; 2014. https://www.skybrary.aero/bookshelf/books/2882.pdf (Accessed 20 April 2018).
58. Braithwaite J, Wears RL, Hollnagel E. Resilient health care: Turning patient safety on its head. *Int J Qual Heal Care*. 2015;27:418-420.
59. Card AJ. The problem with 5 whys'. *BMJ Qual Saf*. 2017;26:671-677. doi:10.1136/bmjqs-2016-005849
60. Dieckmann P, Clemmensen M, Lahlou S. How the medication room really dispenses the medication. In: *Resilient Health Care Net (RHCN) Meeting*. ; 2016. http://resilienthealthcare.net/onewebmedia/Dieckman_RHCN-5.pdf (Accessed 5 April 2018).
61. Dekker S. *Just Culture: Restoring Trust and Accountability in Your Organization*. Boca Raton (FL): CRC Press; 2016.

62. Dekker SWA, Hugh TB. A just culture after Mid Staffordshire. *BMJ Qual Saf*. 2014;23:356-358. doi:10.1136/bmjqs-2013-002483
63. Fairbanks RJ, Wears RL, Woods DD, et al. Resilience and resilience engineering in health care. *Jt Comm J Qual Patient Saf*. 2014;40:376-383.
64. Bracho A. People Are Solutions, Not Problems and Other Chronic Health Lessons Learned. http://www.ihi.org/communities/blogs/people-are-solutions-not-problems-and-other-lessons-learned (Accessed 21 April 2018).
65. Hollnagel E. *Introduction to the Resilience Analysis Grid (RAG)*.; 2015. http://erikhollnagel.com/onewebmedia/RAG Outline V2.pdf (Accessed 5 April 2018).
66. Clay-Williams R, Hounsgaard J, Hollnagel E. Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implement Sci*. 2015;10:125.
67. Baines RJ, Langelaan M, de Bruijne MC, et al. Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ Qual Saf*. 2013;22:290-298.
68. Landrigan C, Parry G, Bones C, et al. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med*. 2010;363:2124-2134.
69. Langelaan M, Broekens M, de Bruijne M, et al. *Monitor Zorggerelateerde Schade 2015/2016: Dossieronderzoek Bij Overleden Patiënten in Nederlandse Ziekenhuizen*.; 2017. https://www.nivel.nl/sites/default/files/bestanden/Rapport_Monitor_Zorggerelateerde_Schade_2017.pdf (Accessed 5 April 2018).
70. Vincent CA. Analysis of clinical incidents: a window on the system not a search for root causes. *Qual Saf Heal Care*. 2004;13:242-243.
71. Huzzard T, Hellström A, Lifvergren S. Whole System in the Room: Toward Systems Integration in Healthcare. *Health Commun*. 2017;0:1-9.
72. Saurin TA. Removing Waste While Preserving Slack: The Lean and Complexity Perspectives. In: LC3 2017 Volume II – Proceedings of the 25th Annual Conference of the International Group for Lean Construction (IGLC), Walsh, K., Sacks, R., Brilakis, I. (eds.), Heraklion, Greece, pp. 217-224.
73. Hounsgaard J. Using FRAM as a Quality Improvement Tool in Health Care. In: *The FRAMily Meeting*. Munich, Germany; 2013. http://functionalresonance.com/onewebmedia/FRAMily_2013_Hounsgaard.pdf (Accessed 20 April 2018).
74. Catchpole K, Neyens DM, Abernathy J, Allison D, Joseph A, Reeves ST. Framework for direct observation of performance and safety in healthcare. *BMJ Qual Saf*. 2017;26:1015-1021. doi:10.1136/bmjqs-2016-006407
75. Braithwaite J, Churruca K, Ellis L, et al. Complexity Science in Healthcare - Aspirations, Approaches, Applications and Accomplishments: A White Paper. Vol 1. Sydney, Australia; 2017. http://aihi.mq.edu.au/resource/complexity-science-healthcare-white-paper (Accessed 5 April 2018).
76. Reed JE, Howe C, Doyle C, et al. Simple rules for evidence translation in complex systems: A qualitative study. *BMC Medicine*. 2018;16:92. doi: 10.1186/s12916-018-1076-9

Chapter 12

Summary

SUMMARY

Quality and safety improvement is a relatively novel discipline in healthcare practice and research that solidified in the early 21st century. Since then, various systems have been installed to collect information on various types of adverse outcomes, such as adverse events, incidents and patient complaints. Data from these systems can be used to evaluate care delivered to individual cases as well as to study aggregated data for patterns, trends and other insights. However, as described in **Chapter 1,** more research is warranted to assess whether these systems actually meet the objective of continuous, systemwide learning and improvement. It was expected that existing practices could benefit from individual optimization as well as better integration, because most of this intelligence is currently stored and used in isolation. Specific research questions of this PhD thesis included:

How can we learn most effectively from various types of adverse outcomes:

(i) based on case discussions at morbidity and mortality conferences;

(ii) by integrating available information sources (e.g., incidents, patient experiences);

(iii) in the context of everyday practice that produces adverse as well as desired outcomes; in order to continuously improve healthcare?

The first three studies presented in this PhD thesis focused on learning from morbidity and mortality conferences (M&M), during which clinicians discuss individual cases with adverse outcomes, in order to improve care for future patients (research question i).

In **chapter 2**, an American and a European academic surgical department with a long tradition of M&M practice were studied using a mixed-methods approach, including observations and surveys among 135 professionals attending M&M. Despite profound differences in the format and organization of the conference, both departments shared the same expectations and challenges. Most participants felt that the educational objective was successfully met, but more was still expected from the conference's focus on, and function for, quality improvement (QI). Yet, respondents from the site with a more active moderator and dedicated QI committee were more positive about these aspects than other respondents. In addition to confirming the well-known practice variation in M&M, this study provides indications that specific challenges for M&M might be more universal, and illustrates how practice variation can be deployed to study strengths and challenges of different formats.

The qualitative study in **chapter 3** sought to examine the more human factors involved in M&M practice, specifically identifying factors that influence M&M success, defined as a conference that drives learning and improvement. A total of 57 facilitators and barriers across 17 themes were identified based on qualitative analysis of 12 semi-structured interviews with a purposive sample of clinicians. While some of these factors related to organizational aspects, many others represented individual or team factors, such as personal motivation and group dynamics. Four team-level factors were perceived as having both positive and negative po-

tential, including 'team spirit', 'hierarchy', 'audience composition/size' and 'multidisciplinary participation'. This study also provided indications on key elements of the desired atmosphere for M&M, many of which were related to the use of 'soft skills' (e.g. people or communication skills) to encourage and facilitate participation and input from the audience. Taken together, the barriers and facilitators appeared to affect whether one is adequately *informed*, *motivated* and *enabled* to learn and realize plans for improvement through M&M. Based on the study findings, a set of actionable recommendations was formulated, each targeting one or more of these three pathways to M&M success.

Chapter 4 presented a study that assessed the frequency, type and recurrence of lessons for future patient care identified at M&M, exploring whether these could serve as a measure of success. This study demonstrates how systematic documentation of lessons learned at M&M can be used to monitor what is learned and not learned at M&M, revealing areas for which lessons may be more difficult to realize and sustain. Over a period of 8 years, 318 lessons had been drawn from evaluations of a total of 10,883 adverse events (AEs) at weekly M&M meetings. Lessons were primarily identified for AEs that were more severe, related to (surgical) treatment, occurring in nonemergent, lower risk cases. Although most lessons concerned intraoperative technical issues with individual-level improvement, lessons that recurred over time were mostly related to postoperative and medication issues involving various disciplines, such as anticoagulation management. Thereby, this study provides empirical evidence that M&M has a tendency to focus on individual, technical issues, with challenges to realize and sustain improvement at the level of the wider system. Additional interviews with clinicians indicated that feelings of ownership and control may partially be responsible for this unevenly distributed focus.

Studies in chapters 5 through 7 assessed how the various data sources that are currently available in many hospitals, such as from incident reporting and patient surveys, could be optimally used for learning and improvement (research question ii). These studies linked data sources at the patient level which are usually isolated from each other, to explore how closer integration of these data could enhance efforts to learn and improve using this intelligence.

In **chapter 5**, data from incident and adverse event (AE) reporting systems and patient complaints handling were linked for 26,383 inpatient admissions to study relations and clustering of these events at the patient level. The study found that complaints filed for cases with incidents and/or AEs more often addressed problems related to quality and safety rather than relationship problems, which were mostly adressed by complaints for other admissions. For most co-occurring incidents and AEs, no evident clinical relationship was identified. Yet, patients with incidents were at increased risk of (a cascade of) AEs, regardless of whether these events seemed clinically related. Taken together, this study demonstrates how patient-level linkage of currently available data allows a more comprehensive approach to learn from these information, revealing complex relations that otherwise remain obscured, such as incidents

emerging in the context of previous AEs. Current approaches are limited to revealing relations between events that are evident and known; after all, record reviewers or incident reporters only identify an AE as such, when they are able to find a relationship with substandard care or with the specific incident that is reported. However, this study found associations between seemingly unrelated AEs and incidents. This could suggest that these events may be able to increase patient vulnerability and complexity through an underlying mechanism, thereby triggering other, seemingly unrelated, events. Moreover, linked data enables us to study how successful our responses to initial AEs or incidents are at preventing patients from further deterioration, from which we may learn how to enhance our responsive abilities.

Chapter 6 described various problems with using patient complaints at an aggregate level for learning and QI. Although complaint letters provide unique and important information from the patient perspective, they are an elusive source of information (eg, emotive, unstructured), producing data of low and unreliable volume. These specific features of complaint letters complicate efforts to identify the specific problems that underlie the complaint, and thereby prevent formulation of an adequate plan for improvement. It is necessary but particularly difficult to identify whether a problem addressed in a complaint is related to the individual professional or a wider system problem, and whether this is incidental or more structural. This chapter offered suggestions to address these challenges, such as that hospitals could take complaints data out of isolation by integrating them and interpreting them in the context of other QI data and processes. In addition, complaints should be viewed as triggers for participative learning rather than as the sole responsibility of the treating physician, so that learning from complaints is a team effort, akin to the practice of healthcare in general.

Another type of routinely collected data regarding the patient perspective on hospital care is patient experience data. **Chapter 7** presented a study in which patient experience survey data was linked to safety reporting data to study the association between complications (aforementioned 'AEs'), incidents and patient-reported problems as well as overall patient experience. Most patients reporting problems in the survey had no complications nor incidents, confirming that patient feedback serves as a complementary source of information. Although patients with suboptimal experiences more commonly reported problems in the survey if they also had complications/incidents, this did not apply to patients with positive experiences. Among patients reporting problems, those with complications/incidents more commonly reported problems on all experience dimensions, except for 'family involvement' and 'physical comfort' (i.e. pain management), which may reflect that attention to these matters is already increased in cases with complications/incidents. Remarkably, risk of suboptimal experience was lower for patients with only complications/incidents than for patients without any complications/incidents or patient-reported problems, which may also suggest successful responses from staff to meet these patients' needs. Although patient-reported problems independently increased risk of suboptimal patient experience, complications/incidents only did so when combined with patient-reported problems on 'continuity and transition' or 'respect for patient prefer-

ences' dimensions. This finding indicates that increased attention to these matters is required in patients with complications/incidents to ensure positive experiences. Similar to chapter 5, this study illustrates how interpretation of linked data from various sources reveals valuable information for improvement.

Chapter 8 demonstrates how hospital communication data can be used to study patterns in communication between healthcare providers, as well as to provide an indication of workflow interruptions and work intensity. The objective of this study was to examine the number, distribution and content of text pages received by residents and physician assistants from a surgical department at an American tertiary academic hospital. In a period of three months, more than 48,000 text pages had been received, with an average of 3 pages per hour and a maximum of 20 per hour. Services where patients were located on the same floor or hallway exhibited remarkably less paging need per patient than services where patients were located on different floors and parts of the hospital, suggesting that the physical layout of these units may be a target for improvement to streamline communication. Natural language processing was used to quantify paging topics in this large volume of open text data. This revealed that most pages concerned medications, particularly pain medications (e.g. opioids), with pain being the most common symptom in pages. Although the hospital had previously implemented protocols for management of pain medications and a postoperative pain service for additional support, these findings highlighted that the need for paging about pain was greater than for other medical issues. Subsequently, local nursing and medical staff discussed these findings and identified the transition from intravenous to oral medication as a potential source for the great number of pages about pain, and hence as a target for improvement.

The final two chapters presented an extension of current approaches to quality and safety, by expanding the focus of learning from adverse outcomes (e.g. incidents, adverse events) to learning from everyday practice (see also Figure 1.1), which produces both adverse as well as desired outcomes (research question iii).

The study presented in **chapter 9** was one of the first in its kind to use the Functional Resonance Analysis Method (FRAM) to study a routine multidisciplinary process in healthcare, i.e., preoperative anticoagulation management. FRAM aims to understand how a process usually works and thus how it often goes right, which is key to the concept of 'Safety-II' that aims to learn from everyday practice rather than only adverse outcomes. This study demonstrated the usability and applicability of the method to increase insight in key functions for functioning of processes, as well as their interdependencies and variability. An initial FRAM model of work-as-imagined was based on guidelines, after which models of work-as-done were iteratively developed using interviews with involved clinicians from a European and Australian academic cardiothoracic surgery department. The results showed that, in both centers, work-as-done appeared to differ from work-as-imagined, and that control mechanisms had been locally

developed, some of which were only used by individuals. Moreover, the models revealed how the patient's 'function' (i.e. activity or step in the process) was rather isolated, reflecting how both centers relied heavily on patients' memory and compliance.

The viewpoint presented in **chapter 10** aimed to contribute to the application of Just Culture and Safety-II theories to healthcare, with a specific focus on the process of learning from sentinel events. These theories offer guidance on how we could learn from severe and difficult events in a spirit of trust and accountability (Just Culture), with greater appreciation of the underlying process in everyday practice (Safety-II). Because the same people and system are responsible for the frequent desired outcomes as for the specific sentinel event, everyday practice may serve as a more representative starting point for a learning review. Drawing from the Just Culture and Safety-II literature, this chapter presented a set of questions that clinicians could use to guide the aftercare and learning process following sentinel events. These questions direct the focus toward collective recovery, restoration and forward-looking accountability, moving away from individual culpability. This approach more closely aligns with current efforts to support the involved clinicians ('second victims') in the aftermath of sentinel events. The presented framework first directs attention to all victims' hurts and needs, and only thereafter focuses on a learning review, in which the aim is to identify the sources of resilience that make everyday practice go right so that these can be enhanced.

In conclusion, the research in this PhD thesis highlights various challenges for learning from adverse outcomes in healthcare. Learning from individual cases at M&M is hampered by a tendency to focus on individuals rather than underlying system-level issues, and thus may benefit from greater reflectivity that triggers learning with greater appreciation of the context in which professionals work. Additional challenges are posed by cultural factors, such as the dynamics in teams and among disciplines, which underlines the need for more qualitative research on these domains. Sources of data on adverse outcomes often remain isolated from each other, but should be used in closer connection, linked at the patient level, to allow more comprehensive analyses. **Chapter 11** discussed that strengthening efforts to ensure safe care requires a more in-depth understanding of everyday practice and how this usually goes right in a complex adaptive system such as healthcare. This could be approached by, for example, assessing the role of resilient performance of healthcare professionals to ensure safety and high-quality care under the varying circumstances of everyday clinical practice.

Appendix

Dutch summary

PhD portfolio

Author affiliations

List of publications

Curriculum vitae

Acknowledgements

DUTCH SUMMARY

Kwaliteit- en veiligheidsmanagement is een relatief nieuwe discipline die aan het begin van de 21e eeuw een plek verwierf binnen de medische wetenschap en praktijk. Sindsdien zijn er verschillende systemen opgezet om informatie te verzamelen over verschillende soorten ongewenste uitkomsten, zoals complicaties, incidenten en patiëntenklachten. Deze informatie kan worden gebruikt voor zowel het evalueren van de zorg die is geleverd aan individuele casus, als voor het bestuderen van geaggregeerde data voor patronen, trends en andere inzichten. In **hoofdstuk 1** werd de noodzaak beschreven voor meer onderzoek om te beoordelen of deze systemen daadwerkelijk bijdragen aan het doel om continu en systeembreed te leren en verbeteren. De verwachting is dat de huidige methoden an sich kunnen worden geoptimaliseerd maar ook kunnen profiteren van betere integratie, aangezien de meeste informatie momenteel geïsoleerd wordt opgeslagen en onafhankelijk van elkaar wordt gebruikt. Specifieke onderzoeksvragen in dit proefschrift waren:

Hoe kunnen we het meest effectief leren van verschillende soorten ongewenste uitkomsten:

(i) gebaseerd op casusbesprekingen tijdens complicatiebesprekingen;

(ii) door bestaande informatiebronnen te integreren (bijv., incidenten, patiëntervaringen);

(iii) in de context van de alledaagse praktijk waar zowel gewenste als ongewenste uitkomsten uit voortkomen;

om hiermee continu de gezondheidszorg te verbeteren ?

De eerste drie studies in dit proefschrift onderzochten het leerproces tijdens complicatiebesprekingen, waar individuele casus met ongewenste uitkomsten worden besproken om de zorg voor toekomstige patiënten te verbeteren (onderzoeksvraag i).

In **hoofdstuk 2** werden een Amerikaanse en Europese academische chirurgische afdeling met een lange traditie van complicatiebesprekingen bestudeerd middels observaties en enquêtes onder 135 zorgverleners die deelnemen aan de complicatiebespreking. Ondanks uitgesproken verschillen tussen beide afdelingen in de opzet en organisatie van de bespreking, deelden zij dezelfde verwachtingen en uitdagingen. De meeste deelnemers vonden dat het leerdoel van de bespreking voldoende behaald werd, maar hun verwachtingen ten aanzien van een focus op - en functie voor - kwaliteitsverbetering werden nog onvoldoende waargemaakt. Wel waren de respondenten van de afdeling waar een actievere gespreksleider en een speciale kwaliteitsverbetercommissie bestond positiever over deze aspecten dan de andere respondenten. Deze studie bevestigt de welbekende praktijkvariatie in complicatiebesprekingen, maar toont ook dat specifieke uitdagingen voor deze bespreking mogelijk meer universeel zijn en dat deze praktijkvariatie kan worden gebruikt om sterke punten en uitdagingen van verschillende besprekingen te onderzoeken.

Het doel van de kwalitatieve studie in **hoofdstuk 3** was om de meer menselijke factoren te onderzoeken die een rol spelen bij de complicatiebespreking en specifiek om de factoren

te identificeren die invloed hebben op het succes van de bespreking, gedefinieerd als een bespreking die leidt tot leren en verbetering. In totaal werden 57 facilitatoren en barrières geïdentificeerd op basis van 12 semi-gestructureerde interviews met een doelgerichte steekproef van clinici. Hoewel sommige van de geïdentificeerde factoren betrekking hadden op hoe de bespreking is georganiseerd, waren er vele andere factoren van invloed op het niveau van individuen of het team, zoals persoonlijke motivatie of groepsdynamiek. Van vier teamfactoren werden zowel positieve als negatieve invloeden ervaren, zoals 'teamspirit', 'hierarchie', 'publiekssamenstelling en -omvang', 'multidisciplinaire deelname.' Deze studie biedt aanwijzingen voor noodzakelijke elementen ten aanzien van het wenselijke klimaat voor complicatiebesprekingen, waarvan vele gerelateerd zijn aan het gebruik van 'soft skills' (bijv. sociale of communicatieve vaardigheden) om deelname en inbreng van het publiek te stimuleren en faciliteren. In het algemeen bleken de barrières en facilitatoren impact te hebben op de mate waarin men adequaat *geïnformeerd, gemotiveerd* en *in staat* is om te leren en verbeterplannen te realiseren via de complicatiebespreking. Op basis van de studieresultaten werd een lijst van praktische aanbevelingen opgesteld die elk gericht zijn op een of meer van deze randvoorwaarden voor een succesvolle complicatiebespreking.

Hoofdstuk 4 presenteerde een studie naar de frequentie, soort en terugkeer van lessen voor toekomstige patiëntenzorg die volgden uit complicatiebesprekingen, om te onderzoeken of deze zouden kunnen fungeren als maat voor succes. Dit onderzoek toont hoe het systematisch documenteren van de lessen uit complicatiebesprekingen kan worden gebruikt om te monitoren wat er wel en niet wordt geleerd tijdens de bespreking, waarmee inzichtelijk kan worden gemaakt welke op gebieden lessen moeilijker te realiseren of borgen zijn. Gedurende een periode van 8 jaar werden 318 lessen geformuleerd op basis van het evalueren van in totaal 10.883 complicaties tijdens wekelijkse complicatiebesprekingen. Lessen werden met name getrokken uit complicaties met hogere ernst, gerelateerd aan (chirurgische) behandelingen, voorkomend in non-urgente en lager risico patiënten. Alhoewel de meeste lessen gingen over intra-operatieve technieken met verbeteringen op het gebied van het individu, waren de meeste lessen die herhaaldelijk terugkeerden gerelateerd aan postoperatieve en medicamenteuze onderwerpen met multidisciplinaire betrokkenheid, zoals antistollingsbeleid. Hiermee levert deze studie empirisch bewijs voor het feit dat complicatiebesprekingen de neiging hebben om te focussen op individuele, technische onderwerpen, met uitdagingen om verbeteringen op het systeemniveau te bereiken en te behouden. Aanvullende interviews met clinici gaven aan dat gevoelens van eigenaarschap en controle deels verantwoordelijk zouden kunnen zijn voor deze onevenwichtige focus.

De studies in hoofdstukken 5 tot en met 7 waren gericht op het leren van complicaties in de context van data over andere ongewenste uitkomsten, zoals incidenten en patiëntervaringen. Onderzocht werd hoe de huidige informatiebronnen in ziekenhuizen optimaal gebruikt zouden kunnen worden (onderzoeksvraag ii). Deze studies koppelden verschillende data

bronnen op patiëntniveau die normaliter geïsoleerd van elkaar zijn, om te onderzoeken hoe betere integratie van deze informatie de leer- en verbeterprocessen zou kunnen ondersteunen.

In **hoofdstuk 5** werden data van het incidentmeldingssysteem, de complicatieregistratie en gearchiveerde patiëntenklachten gekoppeld voor 26.383 ziekenhuisopnames om relaties en clustering te bestuderen op patiëntniveau. Dit onderzoek wees uit dat klachten gemeld voor opnames met incidenten en/of complicaties vaker problemen addresseerden op het gebied van kwaliteit en veiligheid dan op het gebied van relaties, zoals bij klachten voor de overige opnames het geval was. Voor de meeste incidenten en complicaties die samen voorkwamen in dezelfde opnames kon geen klinische relatie tussen deze gebeurtenissen worden gevonden. Echter, voor patiënten met incidenten was het risico op (een cascade van) complicaties groter, ongeacht of deze klinisch gerelateerd leken. Dit onderzoek demonstreert hoe koppeling van reeds beschikbare informatiebronnen op patiëntniveau een meer integrale aanpak voor het leren van deze informatie mogelijk maakt en complexe relaties zichtbaar maakt die anders buiten beeld blijven, zoals incidenten die ontstaan in de context van eerdere complicaties. De huidige methoden voor dossieronderzoek en incidentmeldingen zijn beperkt tot het aantonen van slechts de evidente en reeds bekende relaties: immers, complicaties worden enkel als dusdanig herkend wanneer dossieronderzoekers een relatie zien met suboptimale zorg of wanneer incidentmelders een relatie zien met het specifieke incident. Deze studie vond echter associaties tussen ogenschijnlijk ongerelateerde complicaties en incidenten. Dit kan erop wijzen dat incidenten en complicaties mogelijk via een onderliggend mechanisme de kwetsbaarheid en complexiteit van patiënten kunnen vergroten en daarmee aanleiding kunnen geven tot andere, ogenschijnlijk ongerelateerde, gebeurtenissen. Bovendien biedt datakoppeling de mogelijkheid om onderzoek te doen naar het succes van reacties op initiële complicaties of incidenten waarmee wordt voorkomen dat de situatie van kwaad tot erger wordt voor patiënten. Hiermee kunnen de responsieve capaciteiten verder worden verbeterd.

Hoofdstuk 6 beschreef de verschillende problemen die zich voordoen bij het geaggregeerd gebruik van patiëntenklachten voor leren en kwaliteitsverbetering. Hoewel klachtenbrieven unieke en belangrijke informatie bevatten vanuit het patiëntenperspectief, zijn zij ook een ongrijpbare bron van informatie (o.a., emotioneel, ongestructureerd), wat data oplevert met lage en onbetrouwbare volumes. De specifieke eigenschappen van klachtenbrieven maken het lastig om de specifieke problemen die aan een klacht ten grondslag liggen te identificeren en tot een geschikte oplossing of verbetering te komen. Het is noodzakelijk maar bijzonder ingewikkeld om te bepalen of een probleem dat is benoemd in een klacht, gerelateerd is aan de individuele zorgverlener of aan een breder systeemprobleem, en of dit een incidenteel dan wel meer structureel probleem betreft. Dit hoofdstuk biedt suggesties om deze uitdagingen te addresseren, bijvoorbeeld door klachtendata uit het isolement te halen door deze te koppelen met - en interpreteren in de context van - andere kwaliteitsdata en -processen. Daarnaast zouden klachten moeten worden gezien als een aanleiding voor gezamenlijk leren in plaats

van als individuele verantwoordelijkheid van de behandelaar, zodat leren van klachten een teamprestatie wordt, zoals de gezondheidszorg in het algemeen.

Een ander soort routinematig verzamelde data over het patiëntenperspectief op de ziekenhuiszorg zijn patiëntervaringen. **Hoofdstuk 7** betreft een studie waarin data van een enquête naar patiëntervaringen werden gekoppeld aan veiligheidsmanagement data om de associatie te onderzoeken tussen complicaties, incidenten en door de patiënt gerapporteerde problemen en algehele ervaringen. De meeste patiënten die problemen in de enquête rapporteerden hadden geen complicaties of incidenten, wat bevestigt dat feedback van patiënten een aanvullende bron van informatie is. Alhoewel patiënten met een suboptimale algehele ervaring vaker problemen rapporteerden in de enquête wanneer zij ook complicaties of incidenten hadden, was dit niet van toepassing op patiënten met een positieve ervaring. Onder patiënten die problemen rapporteerden, meldden diegenen met complicaties/incidenten vaker problemen op alle ervaringsdimensies, behalve 'betrokkenheid van familie' en 'fysiek comfort' (pijnbestrijding), wat zou kunnen reflecteren dat er reeds meer aandacht voor deze zaken bestaat in opnames met complicaties/incidenten. Het was opmerkelijk dat het risicio op een suboptimale ervaring lager was voor patiënten met complicaties/incidenten dan voor patiënten zonder enkele complicaties, incidenten of patiënt-gerapporteerde problemen, wat zou kunnen suggereren dat de zorgverleners reeds succesvol zijn in het voldoen aan de behoeften van deze patiënten. Alhoewel de aanwezigheid van patiënt-gerapporteerde problemen het risico op een suboptimale patiëntenervaring onafhankelijk verhoogde, deed de aanwezigheid van complicaties/incidenten dit alleen wanneer er ook patiënt-gerapporteerde problemen bestonden op het gebied van 'continuiteit en transitie' of 'respect voor patiëntenvoorkeuren'. Deze bevinding zou kunnen wijzen op het feit dat er meer aandacht voor deze aspecten vereist is bij patiënten met complicaties/incidenten om een positieve patiëntenervaring te garanderen. Net als **hoofdstuk 5**, illustreert deze studie hoe interpretatie van gekoppelde data van verschillende informatiebronnen waardevolle inzichten voor kwaliteitsverbetering oplevert.

Hoofdstuk 8 onderzocht hoe communicatie data uit ziekenhuizen kan worden gebruikt om patronen in communicatie tussen zorgverleners te bestuderen en als indicatie voor onderbrekingen of verstoringen en intensiteit van het werk. Het doel van deze studie was om het aantal, de verdeling en de inhoud van de tekstberichten te onderzoeken die werden ontvangen door arts-assistenten en physician assistants van een chirurgische afdeling van een derdelijns academisch ziekenhuis in de Verenigde Staten. In een periode van drie maanden werden meer dan 48.000 tekstberichten ontvangen met een gemiddelde van drie berichten per uur en een maximum van 20 per uur. Subafdelingen waar patiënten waren gelocaliseerd op dezelfde verdieping of gang toonden opvallend minder behoefte aan het versturen van berichten dan subafdelingen waar de patiënten zich bevonden op verschillende verdiepingen of delen van het ziekenhuis, wat veronderstelt dat de ruimtelijke indeling van afdelingen een doelwit voor verbetering kan zijn om de communicatie te stroomlijnen. Met behulp van 'natural language

processing' werden de onderwerpen van de tekstberichten geïdentificeerd binnen dit grote volume aan vrije tekst data. Dit wees uit dat de meeste berichten gingen over medicatie, met name pijnmedicatie (bijv. opioïden) en dat pijn het meest voorkomende symptoom in berichten was. Alhoewel het ziekenhuis eerder al protocollen voor medicamenteuze pijnbestrijding en een postoperatief pijnteam voor aanvullende ondersteuning had geïmplementeerd, markeren deze studieresultaten dat de noodzaak om berichten over pijn te sturen groter bleef dan voor andere medische onderwerpen. Deze resultaten zijn vervolgens door locale medische en verpleegkundige zorgverleners besproken en zij identificeerden de transitie van intraveneus naar orale medicatie als mogelijke bron voor dit grote aantal berichten over pijn, en dus als doelwit voor verbetering.

De laatste twee hoofdstukken presenteerden een aanvulling op de huidige benadering van kwaliteit en veiligheid, waarbij de focus voor leren van ongewenste uitkomsten (bijv. incidenten, complicaties) wordt verbreed naar het leren van de alledaagse praktijk (zie ook figuur 1.1.), waaruit zowel ongewenste als gewenste uitkomsten voortkomen (onderzoeksvraag iii).

Het onderzoek in **hoofdstuk 9** is een van de eerste studies waarbij de 'Functional Resonance Analysis Method' (FRAM) werd toegepast om een routinematig multidisciplinair proces in de zorg, namelijk preoperatief antistollingsmanagement, te bestuderen. FRAM heeft als doel om te begrijpen hoe een proces normaliter werkt en hoe het meestal goed gaat, wat fundamenteel is binnen het concept 'Safety-II' dat poogt te leren van de alledaagse praktijk in plaats van enkel ongewenste uitkomsten. Deze studie demonstreert de bruikbaarheid en toepasbaarheid van de methode om inzicht te verkrijgen in essentiële activiteiten voor het functioneren van een proces, inclusief variabiliteit en onderlinge afhankelijkheid. Nadat eerst een FRAM model van 'work-as-imagined' werd ontworpen op basis van de richtlijnen, werden modellen van 'work-as-done' ontwikkeld via een iteratief proces op basis van interviews met betrokken clinici van een Europese en Australische academische afdeling voor cardio-thoracale chirurgie. De studieresultaten toonden dat 'work-as-done' verschilde van 'work-as-imagined' in beide centra en dat verschillende controlemechanismen ter plaatse waren ontwikkeld, waarvan sommige slechts werden gebruikt door individuele medewerkers. Bovendien onthulden de modellen dat de 'functie' (d.w.z. activiteit of stap in het proces) van de patiënt bijzonder geïsoleerd was en dat beide centra sterk afhankelijk waren van het geheugen en de therapietrouw van patiënten.

Met het perspectiefartikel in **hoofdstuk 10** is gepoogd bij te dragen aan de toepassing van de theorieën van Just Culture en Safety-II in de gezondheidszorg en specifiek bij het leren van calamiteiten. Deze theorieën bieden een strategie hoe om te gaan met ernstige en moeilijke gebeurtenissen in een sfeer van vertrouwen en verantwoording (Just Culture), met meer oog voor het onderliggende proces in de alledaagse praktijk (Safety-II). Omdat dezelfde mensen en hetzelfde systeem verantwoordelijk zijn voor de frequente gewenste uitkomsten als voor een specifieke calamiteit, zou de alledaagse praktijk een representatiever uitgangspunt kunnen zijn voor een onderzoek ter lering en verbetering. Dit hoofdstuk presenteerde een lijst van

vragen, gebaseerd op de Just Culture and Safety-II literatuur, die clinici kunnen gebruiken in de nazorg en het onderzoek dat volgt op een calamiteit. Deze vragen verschuiven de nadruk van de schuldvraag en individuele verantwoording naar collectief herstel en 'forward-looking accountability'. Deze benadering sluit beter aan bij de huidige inspanningen om de betrokken zorgverleners ('second victims') adequate steun en opvang te bieden na calamiteiten. Het gepresenteerde kader richt eerst de aandacht op de schade en behoeften van alle slachtoffers en daarna pas op nader onderzoek, waarbij het doel is om bronnen van aanpassingsvermogen en veerkracht ('resilience') te identificeren die ervoor zorgen dat de alledaagse praktijk goed gaat, zodat deze kunnen worden versterkt.

Concluderend: het onderzoek in dit proefschrift markeerde verschillende uitdagingen voor het leren en verbeteren op basis van ongewenste uitkomsten in de zorg. Leren van individuele casus tijdens de complicatiebespreking is belemmerd door een neiging om te focussen op individuen in plaats van onderliggende systeemproblemen en dit leerproces zou kunnen profiteren van meer reflectie en grotere waardering van de context waarin zorgverleners werken. Andere uitdagingen worden geïntroduceerd door culturele factoren, zoals de dynamiek in teams en tussen disciplines, hetgeen de noodzaak voor meer (kwalitatief) onderzoek op deze domeinen onderstreept. Informatiebronnen voor ongewenste uitkomsten bestaan vaak gescheiden van elkaar, maar zouden meer gezamenlijk en in context van elkaar, gekoppeld op patiëntniveau, moeten worden gebruikt om uitgebreidere analyses mogelijk te maken. In **hoofdstuk 11** werd onderbouwd waarom het noodzakelijk is om meer te leren van de alledaagse praktijk en hoe dit meestal goed gaat in een complex dynamisch systeem zoals de zorg, zodat met deze kennis de inspanningen die patiëntveiligheid garanderen kunnen worden versterkt. Dit zou kunnen worden benaderd door te onderzoeken in hoeverre aanpassingsvermorgen en veerkracht ('resilient performance') een rol spelen bij het garanderen van veilige en hoogwaardige patiëntenzorg onder de wisselende omstandigheden van de alledaagse klinische praktijk.

PHD PORTFOLIO

	Year
Courses	
- Basic course regulations and organisation for clinical investigators, LUMC, Leiden [1.0 ECTS]	2017
- Communication in Science, LUMC, Leiden [1.5 ECTS]	2016
- Basic Methods and Reasoning in Biostatistics, LUMC, Leiden [1.5 ECTS]	2016
- Lean six sigma yellow belt training, LUMC, Leiden [0.5 ECTS]	2016
- Tripod Beta incident analysis training, Erasmus MC, Rotterdam [0.5 ECTS]	2016
- Advanced Biostatistics for Medical Researchers, BWH Center for Clinical Investigation, Harvard Medical School [3.75 AMA PRA Category 1 credit]	2013
Conferences (scientific presentations and participation)	
- Presentation 'FRAM to study work-as-done in Australia and Europe', Resilient Health Care Net meeting, Middelfart, Denmark	2018
- Presentation 'Towards Safety-II in hospital care', Resilient Health Care Net meeting, Vancouver, Canada	2017
- Presentation 'Learning from M&M conferences: observational study of frequency, type and recurrence of lessons for patient care', European Surgical Association 24th annual meeting, Bucharest, Romania	2017
- Participant International Forum on Quality & Safety in Healthcare, London, UK	2017
- Participant Resilient Health Care Net Meeting, Middelfart, Denmark	2016
- Participant Functional Resonance Analyis Method (FRAM) workshop, Lisbon, Portugal	2016
- Poster presentation 'Patient feedback driven improvement on the ward', International Forum on Quality & Safety in Healthcare, Gothenburg, Sweden	2016
- Participant High Reliability Organizing (HRO) conference, the Hague	2016
- Poster presentation 'Strengths and key elements of different format for Morbidity & Mortality conferences', International Forum on Quality & Safety in Healthcare, London, United Kingdom	2015
- Presentation 'Learning from patient feedback: transparent improvement in clinical practice' Modernising Postgradute Specialty Training conference, Amersfoort, the Netherlands	2015
Other presentations (invited speaker)	
- Meeting with dr. van Diemen on behalf of Inspectorate (IGJ), HMC, The Hague	2018
- National meeting on healthcare-related harm, NVZ/NFU/FMS/V&VN/Patient Federation, Eemnes	2018
- FRAM workshop for Dutch regional hospitals, MediRisk medical liability insurance, Utrecht	2018
- Educational conference, Department of Gynecology and Obstetrics, LUMC, Leiden	2018
- Educational conference, Department of Gynecology and Obstetrics, HMC, The Hague	2018
- Educational conference, Department of Thoracic Surgery, LUMC, Leiden	2017
- Annual meeting of hospital committee for serious incident analysis, LUMC, Leiden	2017
- Educational conference, Department of Surgery, Groene Hart Hospital, Gouda	2017
- National Construction Safety Day, TBI Holdings Headquarters, Rotterdam	2017
- LUMC Top Research Seminar, Leiden	2017
- Cross-industry Safety Group, den Haag	2017
- TBI Annual Safety Day, TBI construction sites Rijswijk/Rotterdam	2016
- TBI Safety Advisory Board meeting, TBI Holdings Headquarters, Rotterdam	2015
Teaching, supervising	
- Critical Appraisal of a Topic (CAT) project, Daphne Raad	2017
- Research internship, Robyn Heitz	2017
- Research internship, Donald van Bruggen	2016
- Research internship, Barbara Bol	2015

Miscellaneous

- Member taskforce Safety-II, national healthcare-related harm project NVZ/NFU/FMS/V&VN/Patient Federation	2018
- Participant Doctor Meets Director project, Medical Business Foundation, ETZ hospital Tilburg	2017-18
- Member taskforce Patient Safety, Education Council, Federation of Medical Specialists, Utrecht	2016-18
- Member Cross-industry Safety Group, The Hague University of Applied Sciences	2015-18
- Board member JongLUMC (hospital's young professionals network), Leiden	2015-17

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LIST OF PUBLICATIONS

Submitted

de Vos MS, Hamming JF, Boosman H, Marang-van de Mheen PJ. The association between complications, incidents and patient experience in surgical care: retrospective linkage of routine patient experience surveys and safety reporting.

2018

de Vos MS, Hamming JF. From retribution to reconciliation after critical events in surgery. Brit J Surg. Forthcoming 2018.

de Vos MS, Hamming JF, Chua-Hendriks JC, Marang-van de Mheen PJ. Connecting perspectives on quality and safety: patient-level linkage of routinely collected incident, adverse event and complaint data. *BMJ Qual Saf* 2018 Jul 21. [Epub ahead of print]

Damen NL & **de Vos MS**, Moesker M, Braithwaite J, de Lind van Wijngaarden RAF, Kaplan J, Hamming JF, Clay-Williams R. Preoperative anticoagulation management in everyday clinical practice: an international comparative analysis of work-as-done using the functional resonance analysis method. *J Patient Saf* 2018 Jul 7. [Epub ahead of print]

de Vos MS, Hamming JF, Marang-van de Mheen PJ. The problem with using patient complaints for improvement. *BMJ Qual Safety* 2018;27:758-762.

de Vos MS, Marang-van de Mheen PJ, Smith AD, Mou D, Whang EE, Hamming JF. Towards Best Practices for Surgical Morbidity and Mortality Conferences: A Mixed Methods Study. *J Surg Educ* 2018;75:33-42.

Algra AM & **de Vos MS**, Tijdink J. Discipline-overstijgend opleiden: van CanBetter naar CanDiffer. *Medisch Contact* 2018;10:34-36. [article in Dutch]

2017

de Vos MS, Hamming JF, Marang-van de Mheen PJ. Learning From Morbidity and Mortality Conferences: Focus and Sustainability of Lessons for Patient Care. *J Patient Saf* 2017 Oct 30. Epub ahead of print]

de Vos MS, Hamming JF, Marang-van de Mheen PJ. Barriers and facilitators to learn and improve through morbidity and mortality conferences: a qualitative study. *BMJ Open* 2017;7:e01883.

Sandberg EM, Leinweber FS, **de Vos MS,** Linthorst J, Holman FA, Twijnstra ARH, Jansen FW. Optimising postoperative recovery at home; individualised discharge policy and task division between GP and medical specialist. *Ned Tijdschr Geneeskd* 2017;161:D1672. [article in Dutch]

de Vos MS, den Dijker L, Hamming JF. How we can learn better and more safely from serious incidents: translation of 'Just Culture' and 'Safety-II' into clinical practice. *Ned Tijdschr Geneeskd* 2017;161:D1090. [article in Dutch]

2016

Boosman H, **de Vos MS,** Kievit J, Marang-van de Mheen PJ. Patiëntervaringen: meten én verbeteren. *KiZ* 2016;5:22-5. Available from: http://archief.tijdschriftkiz.nl/downloaden/15151/Pati%C3%ABntervaringen-meten-%C3%A9nverbeteren [article in Dutch]

Smith AD, **de Vos MS**, Smink DS, Nguyen LL, Ashley SW. Text paging of surgery residents: Efficacy, work intensity, and quality improvement. *Surgery* 2016;159(3):930-7.

Smith AD, Hawkins AT, Schaumeier MJ, **de Vos MS,** Conte MS, Nguyen LL. Predictors of major amputation despite patent bypass grafts. *J Vasc Surg* 2016;63(5):1279-88.

2015

Hawkins AT, Schaumeier MJ, Smith AD, **de Vos MS,** Ho KJ, Semel ME, Nguyen LL. Concurrent venography during first rib resection and scalenectomy for venous thoracic outlet syndrome is safe and efficient. *J Vasc Surg Venous Lymphat Disord* 2015;3(3):290-4.

2014

de Vos MS, Bol BJ, Gravereaux EC, Hamming JF, Nguyen LL. Treatment planning for peripheral arterial disease based on duplex ultrasonography and computed tomography angiography: consistency, confidence and the value of additional imaging. *Surgery* 2014;156(2):492-502.

de Vos MS, Hawkins AT, Hevelone ND, Hamming JF, Nguyen LL. National variation in the utilization of alternative imaging in peripheral arterial disease. *J Vasc Surg* 2014;59(5):1315-22.
Hawkins AT, Smith AD, Schaumeier MJ, **de Vos MS,** Hevelone ND, Nguyen LL. The effect of surgeon specialization on outcomes after ruptured abdominal aortic aneurysm repair. *J Vasc Surg* 2014;60(3):590-6.

2013

de Vos MS, Smith AD, Shimizu N, Whang EE. Surgical Quality Improvement Book (chapter 5): Morbidity and Mortality Conference: a Weekly Conference Designed to Improve Surgical Quality. Available from: http://www.brighamandwomens.org/Departments_and_Services/surgery/qiChapter5.aspx?sub=0

CURRICULUM VITAE

Marit Suzanne de Vos was born on April 17th, 1990 in Rotterdam, the Netherlands. In 2007, she graduated cum laude from Johan de Witt gymnasium secondary school in Dordrecht, after which she moved to Leiden to attend Medical School. During her studies, she worked as an assistant in post-mortem transplant procedures and participated in other activities, such as debating tournaments and sailing camps. Between September 2010 and 2011, she interrupted her studies to join the board of her student union 'Minerva' full-time, where she was responsible for alumni affairs and development.

In September 2012, Marit again interrupted her medical studies to move to Boston, MA, USA, for a one-year research internship at Brigham and Women's Hospital, under the supervision of Dr. Louis Nguyen, Associate Professor of Surgery at Harvard Medical School. Her research was focused on duplex ultrasonography imaging as a less-invasive alternative to angiography for patients with peripheral arterial disease. During this year, she also served as an abroad columnist for Leiden University's weekly newspaper and as a correspondent for a national radio show about Dutch people living abroad. It was in Boston that Marit developed a great interest in patient safety and quality improvement, particularly through being involved in writing a chapter about morbidity and mortality conferences (M&M).

When Marit returned to Leiden to finish medical school, she decided to focus her research more on quality and safety improvement practices, such as M&M. Besides the two years of medical clerkships, she worked on proposals and funding applications for additional research projects, under supervision of professor Jaap Hamming, who also served as Dutch supervisor during her internship abroad. Perla Marang-van de Mheen joined as co-supervisor. After receiving her M.D. degree cum laude in October 2015, Marit worked as a full-time PhD researcher in the departments of Surgery and Medical Decision Making of Leiden University Medical Center on research committed to learning and improvement in healthcare, as described in this thesis. She also participated in networks connecting safety experts from various industries, such as railway and the oil and gas sector, and joined the national task force committed to facilitate the incorporation of patient safety content in the residency training programs of all Dutch medical specialties.

Marit aspires a career as a gynecologist while additionally pursuing research into healthcare quality and safety improvement. She currently works as a resident (not in training) at the Department of Obstetrics and Gynecology of the Franciscus Gasthuis Hospital in Rotterdam. Recently, Marit was accepted in the Obstetrics and Gynecology Residency Program of Leiden University Medical Center starting April 2019.

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